UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2303-3
Program	Prior Authorization/Medical Necessity
Medication	Daybue™ (trofinetide)
P&T Approval Date	5/2023, 5/2024, 5/2025
Effective Date	8/1/2025

1. Background:

Daybue is a synthetic analog of the amino-terminal tripeptide of insulin-like growth factor-1 (IGF-1) indicated for the treatment of Rett syndrome (RTT) in adults and pediatric patients aged 2 years and older.

2. Coverage Criteria[a]:

A. Initial Authorization

1. Daybue will be approved based on **both** of the following criteria:

   a. Diagnosis of Rett Syndrome (RTT) confirmed by **one** of the following:

      (1) **All** of the following clinical signs and symptoms:

         (a) A pattern of development, regression, then recovery or stabilization
         (b) Partial or complete loss of purposeful hand skills such as grasping with fingers, reaching for things, or touching things on purpose
         (c) Partial or complete loss of spoken language
         (d) Repetitive hand movements, such as wringing the hands, washing, squeezing, clapping, or rubbing
         (e) Gait abnormalities, including walking on toes or with an unsteady, wide-based, stiff-legged gait

      -OR-

      (2) Confirmed genetic mutation in the MECP2 gene

      -AND-

   b. Prescribed by, or in consultation with, **one** of the following:
      (1) Geneticist
      (2) Pediatrician who specializes in childhood neurological or developmental disorders
      (3) Neurologist

Authorization will be issued for 12 months.

B. Reauthorization

1. **Daybue** will be approved based on the following criterion:

    a. Documentation of positive clinical response to Daybue therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. Reference:

1. Daybue [package insert]. San Diego, CA: Acadia Pharmaceuticals, Inc.; September 2024.
2. International Rett Syndrome Foundation. Available at: https://www.rettsyndrome.org/about-rett-syndrome/rett-syndrome-diagnosis/. Accessed March 28, 2025.

Program	Prior Authorization/Medical Necessity - Daybue™ (trofinetide)
Change Control	
5/2023	New program
5/2024	Updated initial approval duration from 6 months to 12 months.
5/2025	Annual review. No changes to clinical criteria.