UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1411-3
Program	Prior Authorization/Notification
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)

   -AND-

   b. Patient is 2 years of age or older

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.

4. Reference:

1. Daybue [package insert]. San Diego, CA: Acadia Pharmaceuticals, Inc.; March 2023.

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