



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1411-2
Program	Prior Authorization/Notification
Medication	Daybue™ (trofinetide)
P&T Approval Date	5/2023, 5/2024
Effective Date	8/1/2024

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:

<p>A. <u>Initial Authorization</u></p> <p>1. Daybue will be approved based on BOTH of the following criteria:</p> <p>a. Diagnosis of Rett Syndrome (RTT)</p> <p style="text-align: center;">-AND-</p> <p>b. Patient is 2 years of age or older</p> <p>Authorization will be issued for 12 months.</p> <p>B. <u>Reauthorization</u></p> <p>1. Daybue will be approved based on the following criterion:</p> <p>a. Documentation of positive clinical response to Daybue therapy</p> <p>Authorization will be issued for 12 months.</p> <p>^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.</p>

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.