Prior Authorization Checklist

acadia connect | Daybue® (trofinetide) oral solution | Daybue® Stix (trofinetide) for oral solution

This checklist may be used to organize and record patient information that may be needed when completing a prior authorization (PA). It is for informational purposes only and does not constitute medical, legal, or reimbursement advice and represents no statement, promise, or guarantee of coverage or payment. Always check the patient's insurance regarding specific requirements when submitting a PA. Individual health insurance policies are frequently updated, and it is the responsibility of the provider and/or their office staff to determine appropriate coding, medical necessity, site of service, and documentation requirements, and to submit appropriate codes, modifiers, and charges for services rendered, as specified by the patient's health insurance.

Initial PA Criteria to Consider

Many policies require you to provide the following information in a PA:

☑ General patient information

- Name
- Date of birth
- Member ID

☑ Patient medical information

- Current diagnosis and patient symptoms
- Any worsening symptoms the patient is experiencing
- Documentation of known renal impairment*
- Documentation of genetic testing when needed by the payer
- Previous medical history
- Treatment history
  - Medications the patient is taking currently and has taken before. Include the drug names, indications, duration of treatment, and reasons for discontinuation
  - Contraindications to any treatments
- Duration of time the patient has been under your care

☑ Diagnosis codes

- Appropriate ICD-10-CM codes to support the patient's diagnosis

Sample ICD-10-CM code†

ICD-10-CM CODE	DIAGNOSIS
F84.2[1]	Rett syndrome[1]

☑ NDC for pharmacy requests

- Include the correct NDC and full product name

Sample NDCs‡

	DAYBUE®	DAYBUE® STIX		
Dosage Strength[2]	200 mg/mL	5,000 mg	6,000 mg	8,000 mg
11-digit NDC[2]	63090-**0**660-01	63090-**0**663-60	63090-**0**664-60	63090-**0**665-60

☑ Required documentation

- Letter of medical necessity
- Medical records, lab reports, chart notes

Please see additional PA criteria to consider listed on the following page

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.
*DAYBUE and DAYBUE STIX are not recommended for patients with severe renal impairment.[2]
†Sample diagnosis codes are for informational purposes only and do not constitute medical, legal, or reimbursement advice and represent no statement, promise, or guarantee of coverage or payment. For a full list of ICD-10-CM codes, please consult the most recent version of the ICD-10-CM manual.
‡NDCs have been "zero-filled" in bold to create an 11-digit code that meets general billing standards.

INDICATION AND IMPORTANT SAFETY INFORMATION

Indication

DAYBUE and DAYBUE STIX are indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older.

Important Safety Information

- **Warnings and Precautions**
  - **Diarrhea:** In a 12-week study and in long-term studies, 85% of patients treated with DAYBUE experienced diarrhea. In those treated with DAYBUE, 49% either had persistent diarrhea or recurrence after resolution despite dose interruptions, reductions, or concomitant antidiarrheal therapy. Diarrhea severity was mild or moderate in 96% of cases. In the 12-week study, antidiarrheal medication was used in 51% of patients treated with DAYBUE.

    Advise patients to stop laxatives before starting DAYBUE or DAYBUE STIX. If diarrhea occurs, patients should notify their healthcare provider, consider starting antidiarrheal treatment, and monitor hydration status and increase oral fluids, if needed. Interrupt, reduce dose, or discontinue DAYBUE or DAYBUE STIX if severe diarrhea occurs or if dehydration is suspected.

See additional Important Safety Information on the following page. Please read the accompanying full Prescribing Information, also available at DAYBUEhcp.com.

Additional PA Criteria to Consider for DAYBUE

☑ Therapeutic services

- Is the patient utilizing therapeutic services (eg, physical therapy, occupational therapy)?

Be sure to provide details, such as the type of service utilized, when the patient started, and why they need it

☑ Additional patient symptoms and concerns

- Are there other disorders/symptoms that the patient is experiencing in relation to Rett syndrome?
- Does the patient have existing kidney problems?

Be sure to provide detailed information regarding other symptoms and renal issues

☑ Reauthorization

- Has this patient already been approved for DAYBUE treatment under this plan?
- Include documentation of sustained improvement or improvements on DAYBUE

Be sure to specify the reason for reauthorization

Providing detailed clinical documentation can help expedite the PA approval for your patients

IMPORTANT SAFETY INFORMATION (cont'd)

- **Warnings and Precautions (cont'd)**
  - **Vomiting:** In a 12-week study, vomiting occurred in 29% of patients treated with DAYBUE and in 12% of patients who received placebo.

    Patients with Rett syndrome are at risk for aspiration and aspiration pneumonia. Aspiration and aspiration pneumonia have been reported following vomiting in patients being treated with DAYBUE. Interrupt, reduce dose, or discontinue DAYBUE or DAYBUE STIX if vomiting is severe or occurs despite medical management.
  - **Weight Loss:** In the 12-week study, 12% of patients treated with DAYBUE experienced weight loss of greater than 7% from baseline, compared to 4% of patients who received placebo. In long-term studies, 2.2% of patients discontinued treatment with DAYBUE due to weight loss. Monitor weight and interrupt, reduce dose, or discontinue DAYBUE or DAYBUE STIX if significant weight loss occurs.
- **Adverse Reactions:** The common adverse reactions (≥5% for DAYBUE-treated patients and at least 2% greater than in placebo) reported in the 12-week study were diarrhea (82% vs 20%), vomiting (29% vs 12%), fever (9% vs 4%), seizure (9% vs 6%), anxiety (8% vs 1%), decreased appetite (8% vs 2%), fatigue (8% vs 2%), and nasopharyngitis (5% vs 1%).
- **Drug Interactions: Effect of DAYBUE and DAYBUE STIX on other Drugs**
  - Trofinetide, a weak inhibitor of CYP3A and an inhibitor of P-gp, can increase the plasma concentrations of CYP3A and/or P-gp substrates (e.g., loperamide), which may increase the risk of adverse reactions associated with these substrates.

    Closely monitor patients when DAYBUE or DAYBUE STIX is administered concomitantly with sensitive CYP3A and/or P-gp substrates for which a minimal increase in substrate plasma concentration (i.e., drugs with a narrow therapeutic index) may lead to serious adverse reactions.
- **Use in Specific Population: Renal Impairment**
  - DAYBUE and DAYBUE STIX are not recommended for patients with severe renal impairment.

DAYBUE is available as an oral solution (200 mg/mL).

DAYBUE STIX for oral solution powder is available in 5,000 mg, 6,000 mg, and 8,000 mg packets.

Please read the accompanying full Prescribing Information, also available at DAYBUEhcp.com.

References: 1. Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. Updated February 9, 2026. Accessed March 6, 2026. https://www.cms.gov/medicare/coding-billing/icd-10-codes. **2.** Acadia Pharmaceuticals Inc. DAYBUE [package insert]. San Diego, CA; 2025.

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