Daybue™ (trofinetide) Prior Authorization Checklist

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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.

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
- 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 NDC

NDC	FULL PRODUCT NAME
63090-660-01[2]	DAYBUE™ (trofinetide)[2]

☑ **Required documentation**

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

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

*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.

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code.

INDICATION AND IMPORTANT SAFETY INFORMATION

Indication

DAYBUE is 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. 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 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.

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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 notes on the patient's response to DAYBUE treatment

> ⓘ 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: 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 if vomiting is severe or occurs despite medical management.
- **Warnings and Precautions: 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 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 on other Drugs**
  - DAYBUE is a weak CYP3A4 inhibitor; therefore, plasma concentrations of CYP3A4 substrates may be increased if given concomitantly with DAYBUE. Closely monitor when DAYBUE is used in combination with orally administered CYP3A4 sensitive substrates for which a small change in substrate plasma concentration may lead to serious toxicities.
  - Plasma concentrations of OATP1B1 and OATP1B3 substrates may be increased if given concomitantly with DAYBUE. Avoid the concomitant use of DAYBUE with OATP1B1 and OATP1B3 substrates for which a small change in substrate plasma concentration may lead to serious toxicities.
- **Use in Specific Population: Renal Impairment**
  - DAYBUE is not recommended for patients with severe renal impairment.

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

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 September 26, 2024. Accessed October 2, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes. **2.** Acadia Pharmaceuticals Inc. DAYBUE [package insert]. San Diego, CA; 2024.