

Helping Your Patients on Their Treatment Journey

A Step-by-Step Guide to Getting Patients Started
on Treatment With **DAYBUE™** (trofinetide)

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INDICATION AND IMPORTANT SAFETY INFORMATION FOR DAYBUE

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.

- **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.

- **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 ($\geq 5\%$ 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 full [Prescribing Information](#), also available at DAYBUEhcp.com.

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Welcome to Acadia Connect®: Support By Your Patient's Side

Acadia Connect is a patient and family support program that connects you, your patients, and their family members with dedicated tools and resources in the treatment journey after patients have been prescribed DAYBUE.

Acadia Connect consists of a dedicated, experienced support team:



Nurse Care
Coordinator

Your Acadia Connect Nurse Care Coordinator provides your office staff access and product information to help your patients start and continue treatment with DAYBUE.



Benefits investigations (BIs)
and access support



Guidance to assist with
prior authorizations (PAs)
and appeals



Information on financial
assistance options



Coordination of
medication delivery
to patients



Support and education
throughout the DAYBUE
treatment journey



Family Access
Manager

The Family Access Manager (FAM) offers access support and educational resources to help navigate treatment with DAYBUE.



Insurance
coverage
education and
support



Information to help
resolve access issues
for DAYBUE, including
information about
PAs and appeals
processes



Support and education
about potential side
effects throughout
the DAYBUE
treatment journey



In-person or virtual
visits to provide
DAYBUE product
education



Our exclusive specialty pharmacy, AnovoRx, will process and fill DAYBUE prescriptions and have clinical pharmacists available 24/7

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Acadia Connect Is Here to Guide You Through Your Patient's Insurance Coverage Process

The patient's health plan may require verification of medical necessity for approval to initiate treatment with DAYBUE.

This guide will walk you through

- The process you and your patients' caregivers may need to follow to obtain insurance coverage for DAYBUE
- The Acadia Connect resources available to assist you at each step

Additional support and resources are available through Acadia Connect to help patients continue treatment with DAYBUE, as well as patient assistance programs.

From starting DAYBUE to providing ongoing support, our team is here to help.

Insurance

Acadia Connect will provide insurance support services to help your patients obtain coverage for DAYBUE.

Financial Assistance

Eligible patients with commercial insurance may pay as little as \$0 per month for DAYBUE after being automatically enrolled in the Acadia Connect[®] Copay Program.* If your patient does not have insurance or DAYBUE is not covered by their insurance plan, we can provide appropriate financial assistance options, such as the Acadia Connect[®] Patient Assistance Program.

Prescription

We partner with AnovoRx, our exclusive specialty pharmacy, to process and fill DAYBUE prescriptions. This process helps your patients start therapy as soon as possible and regularly receive their prescriptions on time.

Delivery

Once AnovoRx finalizes your patient's prescription details, they will schedule the delivery to the location most convenient for your patient's family or caregiver. Acadia Connect will also contact the caregiver regularly to coordinate shipping your patient's refills.

Ongoing Support

Acadia Connect will be in touch regularly with the caregiver to check in and assist them with any changes they may be experiencing with the patient's insurance, financial situation, or prescription delivery.

Visit AcadiaConnect.com to learn more about our personalized support program, designed to help meet the needs of your patients taking DAYBUE

*Terms, conditions, and program maximums apply. This program is not open to patients receiving prescription reimbursement under any federal, state, or government-funded healthcare program. Not valid where prohibited by law.

Steps to Accessing DAYBUE

Once you submit the DAYBUE [Prescription and Enrollment Form](#) to Acadia Connect, there are 4 steps to obtaining coverage for your patient.

The DAYBUE Access Pathway



Step 1 Conducting a Benefits Investigation



Step 2 Submitting a Prior Authorization and/or Letter of Medical Necessity



Step 3 Addressing Denials and Appeals



Step 4 Utilizing Financial Assistance Options

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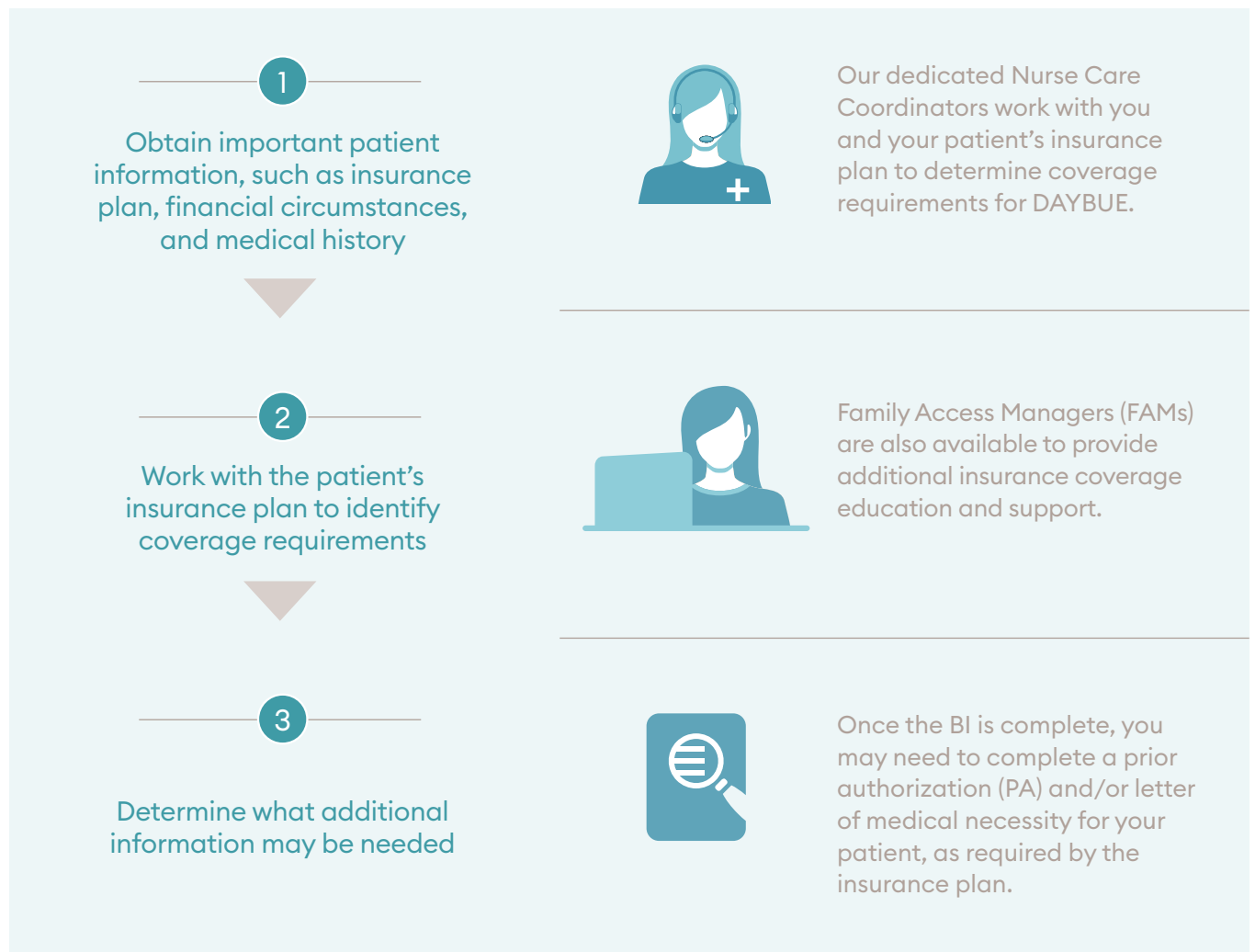
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Conducting a Benefits Investigation (BI)

The first step to obtaining coverage for your patient is a BI with the patient's health plan, conducted by Acadia Connect. The BI will determine whether the patient qualifies for treatment with DAYBUE and identifies any potential limitations.



A BI helps to answer questions about your patient's coverage, such as:

- **Is DAYBUE covered by their insurance?**
- **What additional forms or letters are required to obtain coverage?**
- **What are the expected patient out-of-pocket costs?**

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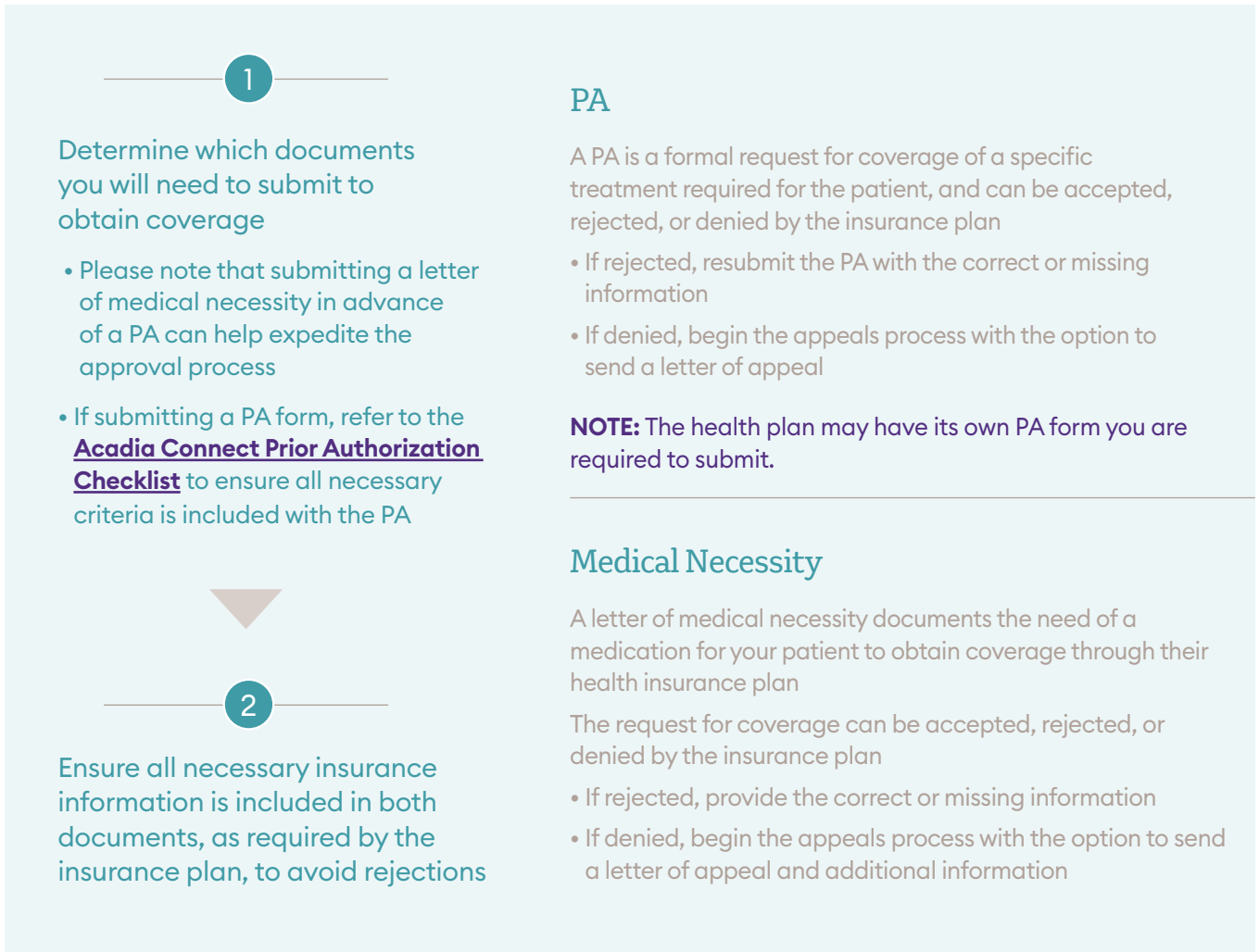
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Submitting a Prior Authorization (PA) and/or Letter of Medical Necessity

After completing a benefits investigation (BI), you may be required to submit a PA form, letter of medical necessity, or both, as required by the insurance plan. Acadia Connect will provide information to help identify the correct documentation as needed.



Both a PA and letter of medical necessity should include information about the patient's medical history, symptoms, and relevant test results

See the next page for more information on how to complete these documents



Step 2



Submitting a Prior Authorization (PA) and/or Letter of Medical Necessity (cont'd)

Completing a PA form or letter of medical necessity thoroughly and accurately is the best way to increase the chances of a positive claim resolution.

Always check to see if the patient's health insurance plan has its own template for you to follow when submitting a PA or letter of medical necessity.

PA

It is important to include all necessary information in the PA to avoid rejections and unnecessary delays. Make sure your PA submission includes

- Appropriate diagnosis codes
- The full product name and National Drug Code (NDC) for DAYBUE. Click here to review details on the [**DAYBUE Product Fact Sheet**](#)
- Accurate and thorough patient information, including medical records and chart notes
- Details on why the treatment is medically necessary
- Additional Rett syndrome healthcare team providers or therapeutic services your patient is utilizing (eg, speech language pathologist, physical therapy)


Click here to navigate to the [Prior Authorization Checklist](#) to help you determine what is needed for your patient's PA.

Letter of Medical Necessity

A letter of medical necessity includes both the patient's medical history and their healthcare provider's rationale for prescribing DAYBUE.

While similar to a PA, the letter of medical necessity focuses on the healthcare provider's medical opinion and is written in a letter format.

Click here to navigate to the [Sample Letter of Medical Necessity](#) that can be customized and used as a template for your patient.



Daybybe
medicals

Acadia

connect

Prior Authorization Checklist

This checklist may be used to request prior authorization that may be needed when completing a prior authorization request. It is not intended to be used as a checklist for the provider. It is intended to be used as a checklist for the provider to ensure that the necessary information is provided to the payer. It is not intended to be used as a checklist for the provider to ensure that the necessary information is provided to the payer. It is not intended to be used as a checklist for the provider to ensure that the necessary information is provided to the payer.

PA Criteria to Consider

1) Provide a brief summary of the following information in a PA:

☐ Patient Information

- Patient ID
- Member ID

☐ Patient Medical History

- Treatment history
- Current medical history, including, but not limited to, the following:
 - Allergies
 - Allergies to drugs, including, duration of treatment, and treatment history
 - Current medical history
 - Current medical history
 - Current medical history

☐ Diagnosis code

- ICD-9-CM diagnosis code
- ICD-9-CM diagnosis code

☐ ICD-9-CM-ICD-10 code*

| ICD-9-CM | DIAGNOSIS | ICD-10 |
|----------|---|--------|
| 430.91 | Major depressive disorder, single episode | 296.2X |

☐ ICD-9-CM-ICD-10 code*

| ICD-9-CM | DIAGNOSIS | ICD-10 |
|----------|---|--------|
| 430.91 | Major depressive disorder, single episode | 296.2X |

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See the next page for information on what to do in the event your request for coverage is denied



Addressing Denials and Appeals

Coverage is denied when the insurance company decides that your patient does not meet the requirements for approval, based on the patient's medical history and documentation provided. The following factors can also contribute to the denial decision:

- Administrative errors on the documents
- Insufficient information regarding medical necessity and patient treatment history
- Incorrect submission process and/or form

If a request is denied, you have the right to appeal the decision. Each insurance plan has its own pathway in place for appealing a coverage denial, so be sure to check with the plan before submitting an appeal to confirm the denial reason(s) and submission requirements.

Initiating the Appeal

To start the appeals process, you will need to submit an:

Appeal Letter

This letter provides additional information regarding your patient, even if you already submitted a letter of medical necessity during the prior authorization (PA) process. This includes clinical information the insurance plan may require based on their reason(s) for denial.

A caregiver may also submit a voice of the patient letter of appeal, an appeal letter written by the caregiver explaining why DAYBUE is needed for the patient's treatment.

If your initial coverage request is unsuccessful, healthcare providers and/or caregivers may write letters to the health insurance plan to appeal the coverage denial of a medication.

These letters should include

- The reason(s) for denial
- Why the coverage denial should be overturned

Visit the **Resources** tab to view samples of these letters that may help with your patient's appeal process.

Always check to see if the patient's health insurance has its own template for you to follow when submitting an appeal letter.

Sample Letter of Medical Necessity for DAYBUE™ (trofinetide)

This sample letter is a guide to help you document the need for a medication for your patient to obtain coverage for it through their health insurance plan. It is not intended to provide reimbursement or guarantee coverage. Individual health insurance policies are frequently updated and it is the responsibility of the physician to ensure that the patient meets the requirements of the plan. It is the responsibility of the physician to ensure that the patient meets the requirements of the plan. It is the responsibility of the physician to ensure that the patient meets the requirements of the plan.

ATTN: (Name of health insurance company)
(PO Box or email address)
(City, State, ZIP code)
(Country)
(Fax)

RE: (Patient name)
(DOB)
(Current age, gender, and name)
(Policy number) (Policy number)
(Group number) (Group number)
(Medicaid number if applicable) (Medicaid number)

Subject: Inpatient to treat with DAYBUE™ (trofinetide)

Dear (Physician medical director contact name),

I am writing to request authorization for my patient, (Patient name), for treatment with DAYBUE. DAYBUE is indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older.

(Patient name) was diagnosed with Rett syndrome on (Month/Day/Year) and has been under my care since (Month/Day/Year). (Patient name)'s medical history, treatment rationale, and documentation are attached to this letter.

Summary of Patient Medical and Treatment History

(Patient name)'s medical history:

Description of (Patient name)'s current symptoms that support diagnosis:

Sample Letter of Appeal of Medical Necessity for (Product Name)

This sample letter is a guide to help you write an appeal for the coverage denial of a medication if a letter of medical necessity was not previously submitted, to your patient's health insurance. It is not intended to provide reimbursement or guarantee coverage. Individual health insurance policies are frequently updated and it is the responsibility of the physician to ensure that the patient meets the requirements of the plan. It is the responsibility of the physician to ensure that the patient meets the requirements of the plan. It is the responsibility of the physician to ensure that the patient meets the requirements of the plan.

(Date of service)

ATTN: (Name of health insurance company)
(PO Box or email address)
(City, State, ZIP code)
(Country)

RE: (Patient Name)
(DOB)
(Current age, gender, and name)
(Policy Number) (Policy number)
(Group number) (Group number)
(Medicaid number if applicable) (Medicaid number)

Subject: Appeal for coverage denial of (Product name)

Dear (Physician medical director contact name),

I am writing to appeal a claim that was denied for my patient, (Patient name), in a letter dated (Month/Day/Year). (Name of health insurance company) stated that (Product name) was not covered for my patient due to (Reason for denial) which is listed in the Explanation of Benefits (attached).

I have reviewed this letter and, based on my medical expertise, ask that you reconsider this decision. (Product name) was approved by the US Food and Drug Administration on (Month/Day/Year) and for (Product indication).

(Patient name) was diagnosed with (Diagnosis name) on (Month/Day/Year) and has been under my care since (Month/Day/Year). Attached to this appeal is a letter of medical necessity that outlines my patient's medical history and current course of treatment. (Patient name) has experienced an inadequate response to the current treatment and therefore, in my clinical opinion, (Product name) is medically appropriate for my patient.

I trust that the enclosed information will establish the medical necessity for approval of this claim. If additional information is required for this request, please contact my office immediately using the information below.

Thank you very much for your attention to this very important matter. I look forward to your response and approval of this treatment request.

Sincerely,

(Physician name) (Credential)
(Physician address)
(Physician phone number)
(Physician email address)

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The Appeal Process

When submitting an appeal, it is important to

- Keep track of dates, methods of correspondence, and reference numbers
- Confirm that any documentation you sent was received (eg, letter of medical necessity) and when
- Record the names of insurance contacts and reviewers with whom you spoke

There are varying levels of appeals, depending on the state and insurance plan.



Some plans may require a member appeal. There may be an option for the member to designate their healthcare provider (HCP) to appeal on the member's behalf

First Level Appeal: Peer-to-Peer Review

After reviewing the reason(s) for denial, you may contact the patient's insurance plan and request reconsideration. You may also request a **peer-to-peer review** conducted by a medical reviewer in order to challenge the decision. The purpose of the first level appeal is to prove that your prior authorization (PA) request meets the insurance plan's requirements and was incorrectly rejected.

Second Level Appeal: Medical Director Review

If your first level appeal is denied, you can request a separate **medical director** to review and reassess the need for approval. The goal of the second level appeal is to further prove that your request should be approved within the insurance plan's coverage guidelines. If needed, you may consider filing a complaint with the state's insurance commissioner.

Independent External Review

If your previous appeals are denied, you may request an external review conducted by an **independent third party** who will review the request and make a final coverage decision. This is done in collaboration with a board-certified physician in the same specialty as the patient's physician.

To achieve a successful resolution, be sure to:



1. Provide all required information and documentation



2. Use language that illustrates why treatment is medically necessary



3. Be aware of common reasons that could lead to a PA denial (see page 9 for reminders of what to include)

Acadia Connect is here to support you through the coverage approval process. For questions, please contact your Nurse Care Coordinator or Family Access Manager (FAM)

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Obtaining Reauthorization for Your Patients

If your patient has already been treated with DAYBUE and requires further authorization to continue treatment, a reauthorization may be necessary.

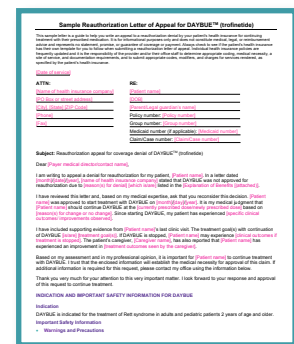
Helpful Tips for Reauthorization Requests

1. Ensure your reauthorization request includes all necessary information required by the insurance plan.
 - Refer to the **Prior Authorization Checklist** for a list of potential criteria that may be required in your request
2. Provide detailed notes on the patient's experience with DAYBUE and any relevant clinical information that may prove the effectiveness of treatment for your patient.
 - Consider asking their caregiver to record daily observations of any changes or improvements experienced while on DAYBUE, which may be relevant later for the reauthorization appeal
3. Keep in mind that insurance plans may require different information for reauthorization requests. Remember to confirm all required information with the insurance plan provider before submitting the request.

If your reauthorization is denied...

Click here to access the **Sample Reauthorization Letter of Appeal** to help you draft an accurate and complete letter of appeal to your patient's insurance company

Always check to see if the patient's health insurance plan has its own template for you to follow when submitting a reauthorization appeal.



When submitting this appeal, be sure to include the reason(s) your reauthorization was previously denied and why they are invalid

Always include your denial's reference number and the specific type of appeal you are requesting (**See the previous page** for full descriptions of each type of appeal review)

Utilizing Financial Assistance Options

Acadia Connect offers several programs and support options to help families and caregivers access DAYBUE for their loved one.

Acadia Connect Financial Programs:



Commercial Copay Program

Through Acadia Connect, eligible commercially insured patients may pay as little as \$0 per month

Eligible patients with commercial insurance may pay as little as \$0 per month for DAYBUE after being automatically enrolled in the Acadia Connect® Commercial Copay Program*



Patient Assistance Programs

For patients who do not have insurance, or situations in which DAYBUE is not covered by their insurance plan, Acadia Connect can provide appropriate financial assistance options, such as the Acadia Connect® Patient Assistance Program

Acadia Connect can check to see if a patient qualifies, based on the program's eligibility criteria



Nurse Care Coordinator Support

Nurse Care Coordinators can connect eligible patients and caregivers to potential third-party resources that may help address financial concerns

*Terms, conditions, and program maximums apply. This program is not open to patients receiving prescription reimbursement under any federal, state, or government-funded healthcare program. Not valid where prohibited by law.



Summary of Resources

Click below to access the resources referenced in this guide at AcadiaConnect.com. For additional assistance, please call Acadia Connect at 1-844-737-2223, Monday to Friday, 8AM to 8PM ET.

Click to open

Prior Authorization Checklist

Click to open

Sample Letter of Medical Necessity (HCPs)

Click to open

Sample Letter of Appeal (HCPs)

Click to open

Sample Reauthorization Letter of Appeal

Click to open

Sample Voice of the Patient Letter of Appeal (Caregivers)

Visit AcadiaConnect.com to learn more about our personalized support program, designed to help meet the needs of your patients taking DAYBUE

Please read the full [Prescribing Information](https://AcadiaConnect.com), also available at DAYBUEhcp.com.