



Understanding Insurance Coverage for DAYBUE® (trofinetide)

A Step-by-Step Guide to Help Caregivers
Learn About Obtaining DAYBUE and Available
Resources for Their Loved Ones



Phone: 1-844-737-2223 Fax: 1-888-385-2748
Learn more at AcadiaConnect.com

Indication and Important Safety Information for DAYBUE

What is DAYBUE?

DAYBUE is a prescription medicine used to treat Rett syndrome in adults and children 2 years of age and older. It is not known if DAYBUE is safe and effective in children under 2 years of age.

What are the possible side effects of DAYBUE?

- **Diarrhea:** Diarrhea is a common side effect of DAYBUE that can sometimes be severe. Diarrhea may cause you to lose too much water from your body (dehydration). Before starting treatment with DAYBUE, stop taking laxatives. Tell your healthcare provider if you have diarrhea while taking DAYBUE. Your healthcare provider may ask you to increase the amount you drink or take antidiarrheal medicine as needed.
- **Vomiting:** Vomiting is a common side effect of DAYBUE. Sometimes vomit can get into your lungs (aspiration), which could cause an infection (aspiration pneumonia). Tell your healthcare provider if you have severe vomiting or if vomiting happens often.
- **Weight loss:** DAYBUE can cause weight loss. Tell your healthcare provider if you notice you are losing weight at any time during treatment with DAYBUE.
- **The most common side effects of DAYBUE were diarrhea and vomiting.** Other side effects include fever, seizure, anxiety, decreased appetite, tiredness, and the common cold. These are not all the possible side effects of DAYBUE. Tell your healthcare provider if you have any side effects that bother you or do not go away.

What should I tell my healthcare provider before taking DAYBUE?

Before taking DAYBUE, tell your healthcare provider about all of your medical conditions, including if you:

- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if DAYBUE will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if DAYBUE passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking DAYBUE.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking DAYBUE with certain medicines may affect how the other medicines work and can cause serious side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You can also call Acadia Pharmaceuticals Inc. at 1-844-4ACADIA (1-844-422-2342).

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

The risk information provided here is not comprehensive. To learn more, talk with your healthcare provider and read the full Prescribing Information, including Patient Information, also available at DAYBUE.com.

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How You Can Use This Guide

Get to Know the Caregiver Insurance Guide for DAYBUE



When your loved one is prescribed DAYBUE, you may have questions about their care, insurance coverage, and available support options. Acadia is here to provide you and your loved one with information, support, and resources throughout the treatment journey.



To find your way through this guide, you can use the tabs on the right to directly go to that specific section. Words that are ***italicized, bold, and black*** can be found in the Glossary to help you understand what that word means.



This guide will provide you with the information you need to understand insurance coverage, set expectations on the process to get DAYBUE covered, and what you and your doctor can do to address challenges along the way. Additionally, you will learn about helpful tips, resources, and programs available through Acadia Connect.

From starting DAYBUE to providing ongoing support, our team at Acadia Connect is here to help you with the following:



Insurance



Financial
assistance



Prescription
delivery



Ongoing
support

acadia
connect

To receive the full support and resources provided by Acadia Connect, you must provide consent. For more information and to provide consent, visit AcadiaConnect.com

Welcome to Acadia Connect®: Support By Your Side

Acadia Connect is a patient and family support program that connects you and your family with educational support and resources before and after DAYBUE is prescribed.

Acadia Connect consists of a dedicated, experienced support team.

The team will help you with

- Understanding your loved one's diagnosis and information regarding DAYBUE
- Answering questions on insurance coverage
- Information on potential financial assistance options
- Support and education throughout the DAYBUE treatment journey



Family Support Educator

The Family Support Educator is dedicated to providing education, support, and resources to help you navigate your loved one's treatment journey.*

- Helps you learn more about your loved one's diagnosis and treatment with DAYBUE
- Provides in-person or virtual one-on-one education
- Answers questions about your insurance coverage
- Helps you prepare for treatment with DAYBUE, including education on side effects
- Keeps you informed on new learning resources, events, and more
- Connects you with other caregivers in the community



Nurse Care Coordinator

The Nurse Care Coordinator is dedicated to helping your loved one get their DAYBUE treatment and providing support whenever you need it.

- Verifies your insurance benefits
- Provides information on potential financial assistance options
- Coordinates with you and AnovoRx Specialty Pharmacy for timely delivery of DAYBUE



Patient Access Manager

The Patient Access Manager is dedicated to helping your doctor with the prescription and insurance process for DAYBUE so that your loved one can get started with treatment.

- Provides your doctor with information on how to get DAYBUE covered for your loved one
- Continues to provide insurance support to your doctor to help reduce gaps in your loved one's treatment journey with DAYBUE

*Family Support Educators cannot provide medical advice or treatment recommendations. These are conversations to have with your doctor, but your Family Support Educator can help you be better prepared for them.



Understanding How to Get Coverage for DAYBUE

How DAYBUE Is Covered By the Insurance Plan

What can the insurance plan approval process for DAYBUE look like? Please remember that while the process below may vary based on different insurance plans, these are the overall steps you can expect to experience for your loved one.

1

Understanding and Verifying Insurance Coverage

Your doctor and their office staff will work with Acadia Connect and the insurance plan to determine your loved one's coverage for DAYBUE.

2

Submitting a Prior Authorization

The doctor's office submits a **prior authorization (PA)** request to the insurance plan, which includes the information required by the plan to review coverage for DAYBUE.

3

Addressing the Prior Authorization Decision

If the insurance plan denies the PA request, your doctor may submit an **appeal** and provide additional information for the plan to consider. If the insurance plan approves the PA, Acadia Connect will contact you to discuss the next steps for getting the DAYBUE shipment.



Review this guide to learn more about the process to get DAYBUE covered and support available to you along the way



Verifying Your Insurance Plan Coverage

After the doctor has prescribed DAYBUE for your loved one, Acadia Connect will contact your insurance plan to perform a **coverage verification**. Verifying your coverage will help to answer the following questions:



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

Acadia Connect will complete the coverage verification for your loved one's treatment with DAYBUE.



Nurse Care Coordinators will contact you to verify your insurance benefits and will also provide information on potential financial assistance options



Family Support Educators will also be available to answer questions about your insurance coverage



Once the verification is complete, Acadia Connect will inform your doctor's office of the outcome, and if they need to provide additional medical information in the form of a PA and/or **letter of medical necessity (LMN)**



During the coverage verification process, you can call your Family Support Educator or insurance plan directly to learn more about your specific benefits and understand the process to get DAYBUE covered.

You can also **call Acadia Connect at 1-844-737-2223**, Monday to Friday, 8AM to 8PM ET, for more information

Submitting a Prior Authorization

Once coverage for DAYBUE has been determined, your doctor may be required to submit additional medical information. Acadia Connect will inform your doctor's office of the information required by the insurance plan for review.

Medical information may need to be provided
in the form of a PA, LMN, or both



What is a Prior Authorization?

A PA is a request by the insurance plan for your doctor to submit additional medical information to obtain approval for coverage.



What is a Letter of Medical Necessity?

An LMN is written by your doctor and explains to the insurance plan why your loved one medically needs DAYBUE. The LMN, along with the PA, will likely contain your loved one's medical history, symptoms, and relevant test results.



While Acadia Connect will work with your doctor to help identify the correct documentation as needed, you can also contact the insurance plan to discuss coverage details and inform them how DAYBUE may be able to help your loved one



Navigating Rejections, Denials, and the Appeals Process

Even if treatment with DAYBUE is medically necessary, the PA may occasionally be rejected or denied. Rejections and denials may commonly be due to

- Administrative mistakes
- Missing information
- Submitting information using the incorrect method



If a PA is rejected, your doctor will need to

- Review and understand the reason for rejection
- Collect and provide the missing information
- Resubmit the PA with the correct and complete information



If a PA is denied, the insurance plan has decided that your loved one does not meet the requirements for approval, based on information submitted. You have the right to appeal the decision and can do the following:

- Contact the doctor's office to discuss why the PA was denied and what you may do to help, or provide additional information
- You can also contact the insurance plan directly or use our "Voice of the Patient Appeal Letter," available on AcadiaConnect.com, and make a case for your loved one on why they need DAYBUE
- Your Family Support Educator will be able to provide you with the appropriate contact information for the insurance plan to submit the letter

Navigating Rejections, Denials, and the Appeals Process (cont'd)

Depending on the state you live in, there may be different levels to submitting an appeal. Your doctor will work with the insurance plan and submit the appeal according to the different levels below.

1st

First Level Appeal

After reviewing the reason(s) for denial, your doctor can contact the insurance plan and ask them to reconsider the decision. They may also ask for a review by a medical reviewer from the insurance plan to challenge the decision. The purpose of the first level appeal is to prove that the PA meets the requirements of the insurance plan and was incorrectly denied.

2nd

Second Level Appeal

If the first level appeal is denied, your doctor can ask for a separate medical director, who was not involved in the first decision, to review the appeal. The goal of the second level appeal is to further prove that DAYBUE should be accepted for your loved one.

3rd

Independent External Review

If the previous appeals are denied, your doctor may ask for an external review by an independent third-party reviewer to make a final coverage decision.



Acadia Connect is here to help your doctor navigate the appeals process. You can also reach out to your Family Support Educator for helpful resources

Getting Reauthorization for Coverage

The insurance plan may require a **reauthorization** for treatment, based on your benefits. This means that in order to continue treatment with DAYBUE, the doctor will need to provide the insurance plan with updated medical information for your loved one.

The reauthorization process works similarly to the PA process, and often utilizes the same forms and submission process. Your doctor should check with the insurance plan to see if there is a specific reauthorization form that should be used.

When a reauthorization is required, you can help by doing the following:

- Be available for any questions your doctor may have while submitting the request
- Provide your doctor with detailed notes on your loved one's experience with DAYBUE and any information that may help demonstrate the benefit of continuing treatment
- Visit AcadiaConnect.com for resources that can help you with tracking this information
- Keep in mind that the insurance plan may require different information for reauthorization requests, and approval may require an appeal



*Kate, age 9, (center) living with **Rett syndrome** with her caregivers (left, right)*

What to Do If DAYBUE Is Not Covered By the Insurance Plan

If the insurance plan does not provide coverage for DAYBUE, do not lose hope. DAYBUE can still be obtained for treatment if you and your doctor's office request a **medical exception**.

A medical exception is a request to use a specific medication for a patient due to medical need, even though it is not covered by the insurance plan.

Some states have laws requiring the response to a medical exception request within a certain period.

Below are some recommendations on what you can do if DAYBUE is not covered on the insurance plan's **formulary**.



Discuss with your doctor what can be done to make a case on your loved one's behalf



Urge your doctor to contact the insurance plan and request a medical exception



Contact the insurance plan, discuss your loved one's treatment needs, and explain how DAYBUE may be able to help. If the insurance plan is through your employer, ask your employer's human resources department to make a case on behalf of your loved one



Connect with patient advocacy groups who may be able to help. You can ask your Family Support Educator about reaching out to these groups



Jill,
Family
Support
Educator

Financial Assistance Programs for DAYBUE

Whether or not your medication is covered, Acadia understands that you may need help with the cost of DAYBUE. Acadia Connect offers a variety of programs and support options to help you get DAYBUE for your loved one.

Financial assistance programs provided by Acadia Connect include



Commercial Copay Program:

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 in certain 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



Acadia Connect Support:

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



Enroll in Acadia Connect to allow our team to provide you with support and help you use these financial assistance programs

*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.

†Terms and conditions apply. An application is required and is subject to review. Submission of an application does not guarantee approval for the program. While Acadia makes every effort to grant aid when needed and appropriate, the program is limited in available resources and may be modified or discontinued at any time, without further notice.

Traveling and Storage Tips for DAYBUE

After your loved one begins treatment with DAYBUE, you may need to travel with the medication (e.g., vacation, holidays). It is important to know how to properly store and travel with DAYBUE.

To properly store DAYBUE:



Refrigerate DAYBUE
between 36°F to 46°F
(2°C to 8°C)



Keep DAYBUE in an
upright position



Do not freeze the
medication



Keep the
child-resistant cap
tightly closed

Be sure to discard any unused DAYBUE oral solution 14 days after first opening the bottle.

Additionally, you can apply for a Transportation Security Administration (TSA) Passenger Support Specialist (PSS) through TSA Cares when traveling with DAYBUE, as it is an oral solution supplied in a 500 mL (approximately 17 oz) bottle. PSS can provide assistance through the security screening process and can also be helpful if your loved one needs a wheelchair, mobility aids, or support devices.



For more information on PSS, terms and conditions, and how to submit a request, visit www.tsa.gov

See Important Safety Information on page 2.



The Health Insurance Marketplace

What to Consider When Choosing an Insurance Plan

It is important to understand what type of insurance plans are available to you and your loved one prescribed DAYBUE. This will help you and your loved one enroll in an insurance plan that best meets your healthcare needs.

Before going over the types of insurance plans available, we will briefly review where you can search for them and the ideal time to enroll.



The Health Insurance Marketplace

The **Health Insurance Marketplace**, also known as the health insurance exchange, is a service that can provide you with options for affordable plans when you cannot obtain it another way (e.g., through your employer).

The health insurance exchange allows you to compare different insurance options, their costs, and coverage. You may qualify for financial assistance to help you pay your monthly premiums for a plan through the health insurance exchange during open enrollment or a qualifying life event.



Open Enrollment

Open enrollment is a specific period during the year where you can sign up for a new insurance plan or change your existing plan. During this time, you can compare various types of health plans and their benefits to determine the plan that works best with your needs and financial situation.

Open enrollment typically occurs in the fall. Beyond the open enrollment window, you can make changes to your coverage under qualifying life events (e.g., marriage, birth of a child). Be sure to check with your and your loved one's insurance for the exact dates of open enrollment.



To learn more about the Health Insurance Marketplace, visit www.healthcare.gov

What to Consider When Choosing an Insurance Plan (cont'd)

There are two main types of insurance plans available in the United States:

Public Insurance Plan

Coverage is provided by the state or federal government, such as **Medicare**, **Medicaid**, or **TRICARE**

- Eligibility based on different factors (e.g., age, income, military status)
- Benefits regulated by government guidelines

Private Insurance Plan

Coverage is provided by a privately owned insurance company through your employer or through direct purchase in the Health Insurance Marketplace

- Provides flexibility in choosing doctors, hospitals, and specialists
- Can come with out-of-pocket expenses, such as **deductibles**, **copayments**, and **coinsurance**

Both **public** and **private** health insurance plans provide a network of doctors for you and your loved one to seek care from. After choosing an insurance plan, be sure to check if a doctor is in-network or out-of-network, as this will impact your out-of-pocket cost.

- **In-network doctor:** If you choose to seek care from a provider who is in-network, you will typically have lower out-of-pocket costs
- **Out-of-network doctor:** If you choose to seek care from a provider who is out-of-network, you will likely be responsible for all or a majority of the cost



Remember that the type of plan and provider you choose, as well as the type of benefits you have, determines the cost of your loved one's care

Public Insurance Plan: Medicare and Medicaid

If you and your loved one are eligible, government-funded insurance plans such as Medicaid and Medicare, may provide you with coverage for DAYBUE



Medicare

Medicare is an insurance program for people ages 65 and older, although it can also provide coverage to younger individuals with certain disabilities. Medicare has set standards for costs and coverage, which means coverage will be the same regardless of the state a person lives in.



Medicaid

Medicaid is an insurance program that provides healthcare coverage for some people with low income, disabilities, and special needs. The program offers benefits that Medicare may not cover (e.g., nursing home care). Eligibility requirements and benefits can differ from state to state.

Each US state operates its own Medicaid program within federal guidelines, and each state has flexibility in the design and administration of its own program. As a result, Medicaid eligibility and benefits vary widely from state to state. In some states, individuals receiving **Supplemental Security Income (SSI)** automatically qualify for Medicaid, while in other states, individuals receiving SSI must separately sign up for Medicaid.



Contact your state's Medicaid office to learn about how you can apply for this program. To get the phone number for your state's office, visit www.medicaid.gov or call 1-877-267-2323

Medicaid Waivers

Medicaid Waivers are a series of actions that allow states to modify their Medicaid programs beyond federal guidelines. These waivers enable states to test new approaches to healthcare delivery, coverage, and financing. The goal is to improve the health and well-being of people in this program while controlling costs.

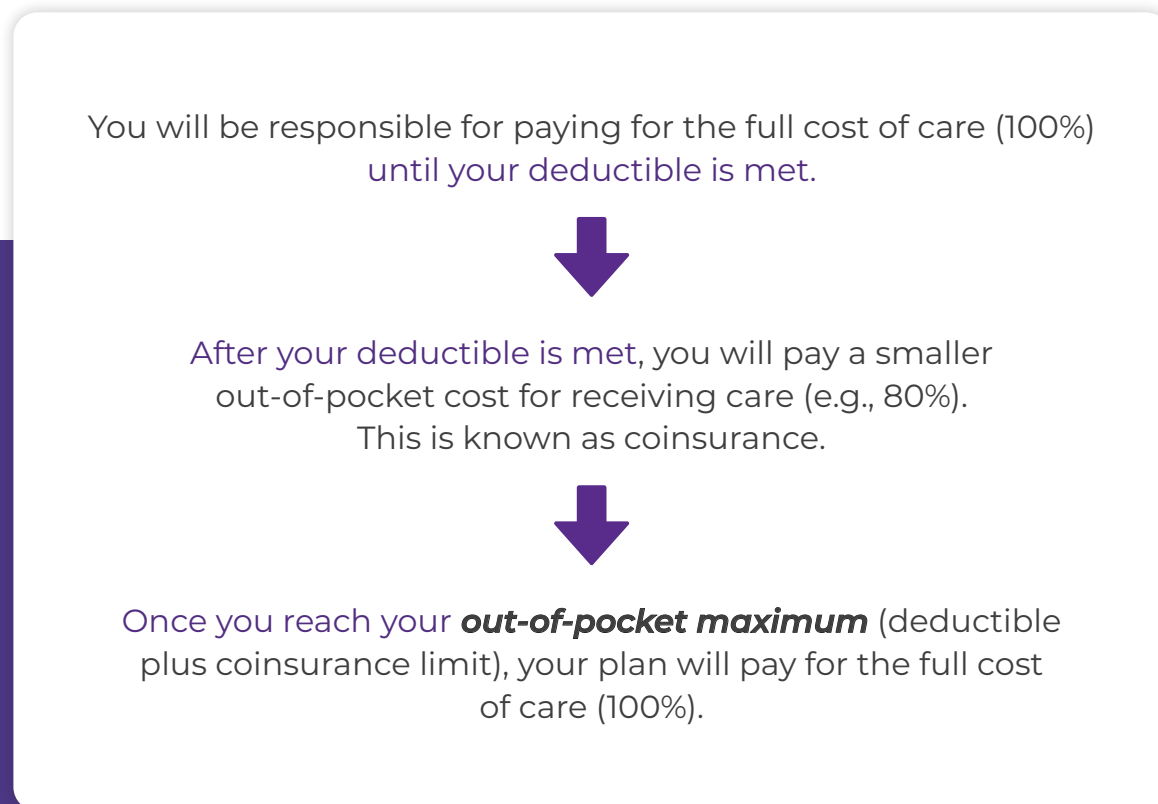


To learn more about Medicaid Waivers, visit Medicaid.gov or Kidswaivers.org for more information

Private Insurance Plan: High-Deductible Health Plans (HDHPs)

A **high-deductible health plan (HDHP)** is a commercial insurance plan with a high deductible. You may have a lower monthly **premium**, but you will be required to cover more of the cost of care before the plan starts to pay its share. HDHPs can also be referred to as Health Savings Account (HSA)-eligible plans.

Below is an example of how the cost can be shared between you and an HDHP:



Additional Resources

Acadia Connect provides you with resources to help you navigate the coverage process and begin treatment with DAYBUE for your loved one. You can view the resources listed on this page by visiting AcadiaConnect.com and DAYBUE.com.

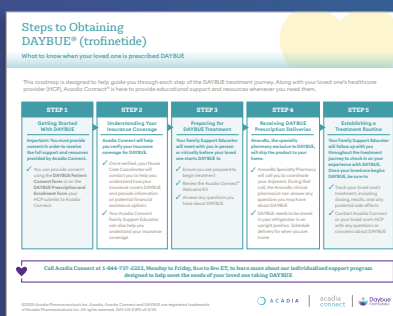
Acadia Connect Resources

Acadia Connect Program Consent form. This document outlines the terms and conditions of the Acadia Connect program, including the use of patient information for research and educational purposes. It includes sections for patient information, consent, and a signature line for the patient or caregiver.

Acadia Connect
Program Consent



Acadia Connect
Overview



Steps to Obtaining
DAYBUE

Sample Voice of the Patient Letter of Appeal. This letter provides a template for patients and caregivers to use when appealing a denial of coverage for DAYBUE. It includes sections for patient information, a statement of the denial, and a request for reconsideration.

Sample Voice of the
Patient Letter of Appeal

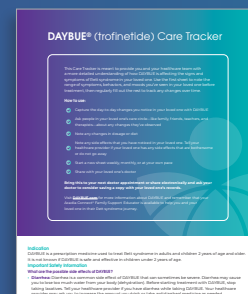
DAYBUE Resources



Taking DAYBUE
Brochure



Daily Treatment
Journal



DAYBUE
Care Tracker

The information provided herein is for informational purposes only and is not a promise of patient assistance, coverage, reimbursement or payment. Please contact Acadia Connect for more information.

Glossary of Terms

Appeal:

A request for the insurance plan to reconsider its decision to deny coverage for medication or service

Coverage verification:

Process to determine a patient or loved one's health coverage and benefits through the insurance plan

Copayment:

A fixed amount a patient or loved one will pay for a specific medication or service, as determined by the insurance plan

Coinsurance:

The percentage a patient or loved one will pay for the cost of receiving healthcare

Deductible:

The amount a patient or loved one will need to pay before the insurance plan starts paying its share of the cost

Formulary:

A list of prescription drugs that are covered by the insurance plan

Health Insurance Marketplace (health insurance exchange):

A service that allows a patient or loved one to search, compare, and enroll in an affordable insurance plan

High-deductible health plan (HDHP):

An insurance plan that has a high deductible, which is the amount a patient or loved one must pay before the plan starts to pay its share

In-network doctor:

A doctor who is covered under the patient or loved one's insurance plan, which can mean paying a lower cost when receiving care. To be covered means they are contracted with and accept the plan

Letter of medical necessity (LMN):

A letter written to the insurance company by the doctor, on behalf of a patient, to demonstrate the clinical need for a drug or service. The LMN will contain the patient's diagnosis, symptoms, medical history, prescription history, and any other relevant medical information for the insurance plan to consider

Medicaid:

A state and federal government-funded insurance program that provides free or low-cost healthcare to patients and families with low income, disabilities, and special needs. Medicaid eligibility and benefits vary by state

Medical exception:

A type of coverage determination for a drug or service that is not covered by the patient or loved one's insurance plan

Medicare:

A federal government-funded insurance program for people 65 years of age and older, certain younger people with disabilities, and people with End-Stage Renal Disease (ESRD)

Out-of-pocket cost:

Cost paid by the patient or loved one that is not reimbursed by the insurance plan. This includes deductibles, coinsurance, and copays

Out-of-pocket maximum:

The deductible plus coinsurance limit the patient or loved one will pay for the year before the insurance plan covers 100% of the cost

Out-of-network doctor:

A doctor who does not participate in the patient's or loved one's insurance plan, which can mean paying a higher cost when receiving care. When a doctor does not participate in an insurance plan, it means the doctor is not contracted with and does not accept the insurance plan

Premium:

The amount the patient or loved one will pay every month for their insurance

Prior authorization:

A request by the insurance plan for your doctor to submit additional medical information to obtain approval for coverage of specific drugs or services

Reauthorization:

A periodic request by the insurance plan for updated medical information from the doctor regarding the patient's treatment progress to ensure the drug or service is still medically necessary

Supplemental Security Income (SSI):

A monthly benefit paid by the Social Security Administration for people with low income, disabilities, or who are 65 years of age or older

TRICARE:

A healthcare program for active duty service members, retirees, and their families



For questions or more information, visit AcadiaConnect.com or call Acadia Connect at 1-844-737-2223, Monday to Friday, 8AM to 8PM ET



See Important Safety Information on page 2 and read the full [Prescribing Information](#), including [Patient Information](#), also available at DAYBUE.com.



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