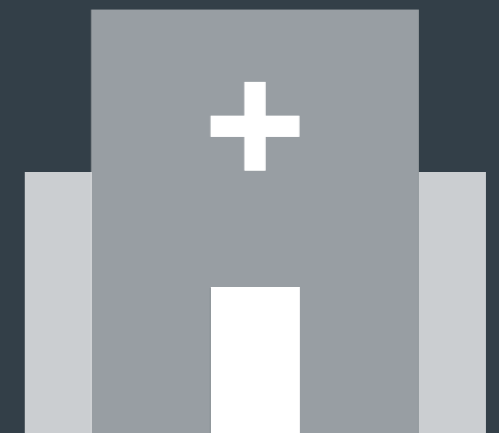




UPLIZNA ACCESS JOURNEY

A RESOURCE TO EDUCATE
HEALTHCARE PROFESSIONALS ABOUT
PATIENT ACCESS AND COVERAGE



Please see Important Safety Information on page 12 and [Full Prescribing Information](#).

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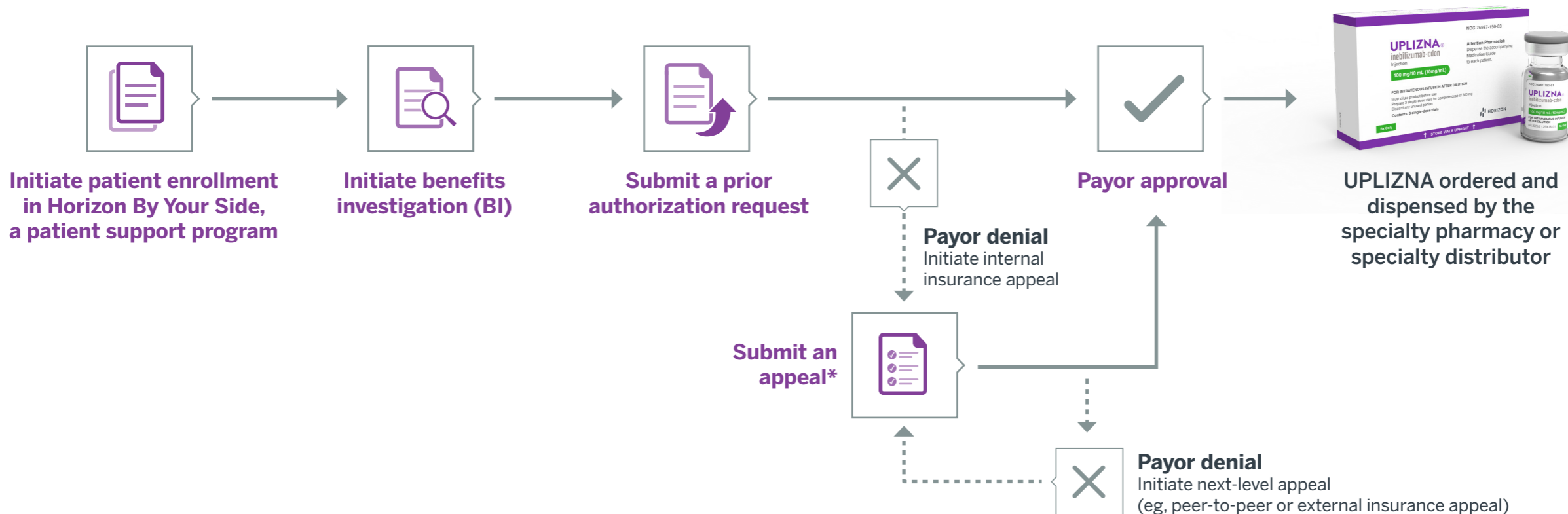




UPLIZNA PATIENT ACCESS ROADMAP

The payor access process, step by step

This resource can help you identify the steps in the access process as well as available resources. You can navigate through the roadmap by clicking on areas of the map or by using the navigation bar above. In each section, you will find more detailed information and resources available for that step of the process.



Horizon By Your Side has team members who educate about navigating insurance processes and accessing treatment on your patient’s behalf



The team at Horizon By Your Side provides resources your patients can rely on throughout their access and treatment journey.

Call **1-833-842-8477** Monday–Friday, 9 AM–8 PM ET or visit www.HorizonByYourSide.com

*Submitting an appeal does not guarantee approval, and this process may need to be repeated.





HORIZON OFFERS PATIENTS A RANGE OF SUPPORT THROUGHOUT THEIR ACCESS AND TREATMENT JOURNEY

Coverage policies may vary, and the team at Horizon By Your Side can help identify policies early in the access process to help ensure maximum efficiency



Horizon By Your Side

A partner your patients can rely on throughout their access and treatment journey that provides a wide array of patient-focused services. The team at Horizon By Your Side may provide nonmedical logistical treatment support and education about the insurance process.



Patient Access Liaison (PAL)

Provides dedicated, one-on-one support for your patient. The PAL works directly with individual patients to answer nonmedical logistical questions and provide support upon enrollment. Additionally, the PAL educates about navigating insurance processes and accessing treatment on your patient's behalf. The PAL has the expertise and tools to support the patient by educating on patient benefits, PA requirements, payor policies, and coding and claim submissions.



Horizon Case Manager

A Case Manager will be assigned to your patient and may also be in touch with your office to make sure important insurance information is properly shared.



Associate Director, Site of Care (ADSOC)

The Site of Care Team establishes business-to-business relationships with sites of care and expands the network of infusion center options. The team educates on coding, billing, and payor access and provides product in-servicing.



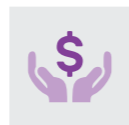
INITIATE PATIENT ENROLLMENT

Many treatments require initial action from the healthcare provider and office staff for patients to get access to UPLIZNA. The team at Horizon By Your Side provides a range of support tailored to meet the individual needs of your patients throughout their access and treatment journey with UPLIZNA.

The Patient Enrollment Form (PEF) is the first step for your patients to receive support from the team at Horizon By Your Side, including:



Researching insurance coverage, PA requirements, and appeal instructions, if denied



Financial assistance for eligible patients

- The Horizon Commercial Co-Pay Program helps eligible commercially insured patients with their UPLIZNA deductibles, co-insurance, and all co-pays associated with the IV infusions
- Co-pay may be as little as \$0 for eligible patients
- For patients with government insurance, like Medicare, independent foundation support might also be an option*



Patient support via a PAL who works directly with individual patients to answer nonmedical logistical questions and provide support throughout their journey



Download the PEF to initiate patient enrollment in Horizon By Your Side.

*Please note that independent foundations establish, administer, and implement the funds, which are separate and apart from Horizon.





CONDUCT A BENEFITS INVESTIGATION

Coverage criteria will vary among health plans and a BI will identify requirements specific to UPLIZNA. A PAL can help educate you and your patient about the insurance process and accessing treatment.



Conducting a benefits investigation may help answer questions about payor coverage

Prescription information

- Is UPLIZNA medically appropriate?
- Is UPLIZNA being prescribed in accordance with generally accepted standards of medical practice?

UPLIZNA coverage

- Is UPLIZNA covered under the medical benefit or pharmacy benefit?

PA

- Will a prior authorization be required for treatment with UPLIZNA?
- If a prior authorization is not required, is predetermination available?
- What is the process for obtaining a prior authorization or predetermination?
- What information will be required, and how long will the process take?
- How long will the prior authorization remain valid?

Benefits coordination

- Does the patient have any other supplemental insurance benefits that would require coordination? Which benefit is primary? Which is secondary?

Patient financial responsibility and out-of-pocket (OOP) costs

- What is the annual deductible amount the patient must meet?
 - Has this amount been met?
 - How much is left?
- What is the patient's co-payment or coinsurance for UPLIZNA?
- Is there a maximum OOP amount that the patient must meet?
 - Has this amount been met?
 - How much is left?



Download the UPLIZNA PA Checklist to help your office organize the information that may be needed for a PA.



CONDUCT A BENEFITS INVESTIGATION (cont'd)



Coding and claims submission

A BI can help answer questions such as:

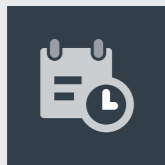
- What are the specific coding and claims submission requirements for prescribing UPLIZNA in this patient's plan?
- What type of documentation is required?

UPLIZNA ICD-10-CM Code*

Code	Description
G36.0	Neuromyelitis optica [Devic]

UPLIZNA NDC Codes

	Code	Quantity	Strength
Intravenous injection	75987-150-03	1 carton containing 3 single-dose vials	100 mg/10 mL
	75987-0150-03		



Reminder: Requirements for coverage will vary among health plans and a BI will identify requirements specific to UPLIZNA as well as your patient's insurance plan.

Once the team at Horizon By Your Side completes the BI, you will receive a Summary of Benefits notification within 1 to 2 business days of insurance verification.

*This may not be the only applicable code for coverage, and using this code does not guarantee coverage. ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.





SUBMIT A PRIOR AUTHORIZATION

The PA process allows the health plan to review the reason for treatment with UPLIZNA and to determine if it is medically appropriate. Clinical documentation requirements will vary among health plans.



Common criteria that a health plan policy may require for a PA:

Diagnosis information

- Diagnosis/ICD-10-CM code
 - Neuromyelitis optica [Devic]/G36.0
- Diagnosis of NMOSD confirmed by positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG) antibodies
- Documentation that the patient is at least 18 years of age
- Documentation that UPLIZNA is prescribed by, or in consultation with, a neurologist



Important: Including a letter of medical necessity with a PA is important and may help avoid delays.

Treatment history

- Documentation of failure or inadequate response to previous therapy (≥ 1 relapse within the last 12 months or ≥ 2 relapses within the last 24 months)
 - If medication was discontinued, list all reasons for discontinuation, including side effects, intolerance, nonadherence, or comorbidities
- For patients already taking UPLIZNA, provide documentation showing clinical improvement

Your office may need to connect with the referring physician to gather the clinical documentation required to complete the PA. The dedicated PAL has the local expertise to provide education about PA, medical exception, or appeal processes.

NMOSD, neuromyelitis optica spectrum disorder.



SUBMIT A PRIOR AUTHORIZATION (cont'd)

The PA process allows the health plan to review the reason for treatment with UPLIZNA and to determine if it is medically appropriate. Clinical documentation requirements will vary among health plans.

PRIOR AUTHORIZATION (PA) CHECKLIST FOR UPLIZNA® (inebilizumab-cdon)

This checklist is for informational purposes only. For health plan-specific criteria, please contact a **Horizon By Your Side** representative. Horizon By Your Side, a patient support program, has team members who educate about navigating insurance processes and accessing treatment on your patient's behalf. Initiate your patient's enrollment in Horizon By Your Side by submitting the Patient Enrollment Form. Your patient must enroll in Horizon By Your Side and provide HIPAA consent to access these patient-focused services and resources.

Although requirements vary by plan, below are common criteria that may be requested for UPLIZNA. Patient Access Liaisons can provide education about navigating insurance processes and accessing treatment during your patient's access journey.


1 Benefits investigation
PA requirements vary between plans. Contact the health plan to understand the process, step therapy requirements, duration of approval, and other relevant information

2 PA requirements

Patient/Provider Information Name Date of birth Health plan Provider name Provider identification number	Some plans may require documentation of specific information, while some may require physician attestation.
Diagnosis Information Diagnosis/ICD-10-CM code* - Neuromyelitis optica [Dewic] G36.0 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) confirmed by positive serologic test for aquaporin-4-immunoglobulin G (AQP4-IgG) antibodies Patient is 18 years of age or older Documentation that UPLIZNA is prescribed by, or in consultation with, a neurologist	Be sure to provide relevant clinical support, such as clinical notes, laboratory results, etc.

INDICATION
UPLIZNA® (inebilizumab-cdon) is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

1 Please see Important Safety Information on page 3 and see Full Prescribing Information.




Thoroughly complete every section of the PA form and review the medical policy carefully, as each health plan may have unique requirements



Provide supporting documentation, including, but not limited to:

- A letter of medical necessity
- Medical records
- Diagnosis of NMOSD confirmed by positive serologic test for AQP4-IgG antibodies
- Clinical/chart notes
- Publications and references



Inquire about how long the process will take once necessary documents have been submitted



Important: Including a letter of medical necessity with a PA is important and may help avoid delays.



Download the UPLIZNA Prior Authorization Checklist for reminders and recommendations for submitting a PA.



Download the Letter of Medical Necessity Template and print it out on your office letterhead.



SUBMIT A PRIOR AUTHORIZATION (cont'd)

[Office letterhead]

[Date]

[Contact name of medical director or other payer representative]
[Contact title]
[Name of health insurance company]
[Mailing address]

Re:
Letter of Medical Necessity for J1823: UPLIZNA[®], injection, inebilizumab-cdon, 1 mg
Patient: [Patient name]
Group/Policy Number: [Number]
Date(s) of Service: [Date(s)]
Diagnosis: G36.0, neuromyelitis optica [Device]

Dear [Contact name or department],

I am writing on behalf of my patient, [Patient name], to document medical necessity for treatment with UPLIZNA[®] (inebilizumab-cdon). UPLIZNA is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. On behalf of [Patient name], I am requesting approval for use and subsequent payment for the treatments.

Medical History and Diagnosis
[Patient name] is a [Age]-year-old [male/female] diagnosed with NMOSD. [Patient name] has been in my care since [DATE]. As a result of NMOSD, my patient [enter brief description of patient history]. Additionally, [Patient name] has tried [previous treatments] and [outcomes]. [If patient has been on UPLIZNA therapy, include outcomes experienced and consider including the effect of continuity of care.] The attached medical records document [Patient name]'s clinical condition and the medical necessity for treatments with UPLIZNA.

- [Diagnosis] ICD-10-CM code: Neuromyelitis optica [Device] G36.0
- [Diagnosis of NMOSD confirmed by positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG) antibodies]
- [Documentation that UPLIZNA is prescribed by, or in consultation with, a neurologist]
- [Documentation of failure or of inadequate response to previous therapy (≥1 relapse in the past 12 months or ≥2 relapses in the past 24 months)]
- [Any relevant clinical/chart notes]

Based on the above facts, I have made the assessment that UPLIZNA is indicated and medically necessary for [Patient name]. The plan of treatment is to administer an initial dose of 300 mg of UPLIZNA via intravenous (IV) infusion on [date], followed [2 weeks before date] by a second 300-mg dose. Subsequent single 300-mg doses of UPLIZNA via IV infusion will follow every 6 months thereafter, starting 6 months from the date of the first infusion.

Please consider coverage of UPLIZNA for [Patient name] and approve use and subsequent payment for UPLIZNA as planned. Please refer to the enclosed Prescribing Information for UPLIZNA. If you have any further

Writing a letter of medical necessity

A patient-specific letter of medical necessity explains the physician's rationale and clinical decision-making in choosing UPLIZNA.

The template letter of medical necessity for UPLIZNA can be customized based on your patient's medical history and demographic information. The template can help your office craft the letter and highlight the medical necessity for your patient.

NOTE: Some health plans may have specific forms that must be completed in order to document medical necessity.



Check with the health plan to identify specific documentation that needs to be submitted with a letter of medical necessity



Provide relevant medical information and attach the patient's medical records and/or supporting documents for health plans to review



Include a copy of the [Full Prescribing Information](#)



Download the Letter of Medical Necessity Template and print it out on your office letterhead.





SUBMIT AN APPEAL

An appeal letter may be needed if a PA for UPLIZNA is denied. When writing an appeal letter, ensure that you address the specific details of the denial reason(s), refer to the letter of denial for specific language regarding the reason for denial, and address any concerns that are patient-specific.

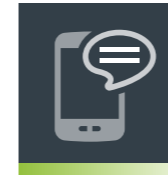
Supplemental documentation may include:

- Relevant clinical/chart notes for your patient
- Recent test results
- Patient lifestyle modifications as a result of living with NMOSD
- Supporting scientific publications/journal articles
- A summary of your recommendation at the end of the letter
- A letter of medical necessity

Make sure you match the exact language from the denial letter. It is imperative to address the specifics of the denial in the appeal letter.

Before you submit your appeal, make sure to:

- Check for any incomplete or missing information, as this is a common reason for denial
- Schedule a peer-to-peer meeting with the health plan
- Contact a PAL to learn about additional resources and next steps in the process



Contact the health plan to learn about the appeal review timeline. Once you have submitted the letter, along with any supporting documentation, most health plans will review and decide on coverage within approximately:



72 HOURS
for urgent care



30 DAYS
for nonurgent care



60 DAYS
for services already provided

To initiate an expedited appeal, contact your patient's health plan to confirm its instructions for expedited requests.



Download the Appeal Letter Template to help your office draft an appeal letter.



Download the Payor Appeal Letter Checklist and Tips to help you through the appeal process.

If a letter of medical necessity was not submitted with the PA, consider including it with the appeal letter.



BEST PRACTICES TO MAINTAIN THROUGHOUT THE ACCESS JOURNEY



DOCUMENT

Keep a record of policy requirements, which may vary considerably among different health plans.



IDENTIFY

Ensure smooth transactions among the provider, health plan, and patient by identifying each health plan’s policy early on.



KNOW

Health plan policies provide clarity for patients on their coverage and OOP expenses.



CONTACT

A PAL is ready to assist you with your questions.



The team at Horizon By Your Side provides resources your patients can rely on throughout their access and treatment journey.

Call **1-833-842-8477** Monday–Friday, 9 AM–8 PM ET or visit www.HorizonByYourSide.com





INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

UPLIZNA® (inebilizumab-cdon) is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

IMPORTANT SAFETY INFORMATION

UPLIZNA is contraindicated in patients with:

- A history of life-threatening infusion reaction to UPLIZNA
- Active hepatitis B infection
- Active or untreated latent tuberculosis

WARNINGS AND PRECAUTIONS

Infusion Reactions: UPLIZNA can cause infusion reactions, which can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash, or other symptoms. Infusion reactions were most common with the first infusion but were also observed during subsequent infusions. Administer pre-medication with a corticosteroid, an antihistamine, and an anti-pyretic.

Infections: The most common infections reported by UPLIZNA-treated patients in the randomized and open-label periods included urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%), and influenza (7%). Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

Increased immunosuppressive effects are possible if combining UPLIZNA with another immunosuppressive therapy.

The risk of Hepatitis B Virus (HBV) reactivation has been observed with other B-cell-depleting antibodies. Perform HBV screening in all patients before initiation of treatment with UPLIZNA. Do not administer to patients with active hepatitis.

Although no confirmed cases of Progressive Multifocal Leukoencephalopathy (PML) were identified in UPLIZNA clinical trials, JC virus infection resulting in PML has been observed in patients treated with other B-cell-depleting antibodies and other therapies that affect immune competence. At the first sign or symptom suggestive of PML, withhold UPLIZNA and perform an appropriate diagnostic evaluation.

Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating UPLIZNA.

Vaccination with live-attenuated or live vaccines is not recommended during treatment and after discontinuation, until B-cell repletion.

Reduction in Immunoglobulins: There may be a progressive and prolonged hypogammaglobulinemia or decline in the levels of total and individual immunoglobulins such as immunoglobulins G and M (IgG and IgM) with continued UPLIZNA treatment. Monitor the level of immunoglobulins at the beginning, during, and after discontinuation of treatment with UPLIZNA until B-cell repletion especially in patients with opportunistic or recurrent infections.

Fetal Risk: May cause fetal harm based on animal data. Advise females of reproductive potential of the potential risk to a fetus and to use an effective method of contraception during treatment and for 6 months after stopping UPLIZNA.

Adverse Reactions: The most common adverse reactions (at least 10% of patients treated with UPLIZNA and greater than placebo) were urinary tract infection and arthralgia.

