

## **UPLIZNA MEDICATION ORDER**

Please complete all attached pages and submit to Horizon Therapeutics via fax at 833-8442-8477.

Signatures by the patient and prescriber are required as indicated.

Completing all lines of the worksheet will significantly ease the authorization process. Once the case is transferred to us, we will contact your office to obtain supporting documentation (including lab results and medical records).

Thank you!

# PATIENT ENROLLMENT FORM

Once complete, submit by fax 1-833-329-8477  
or email [UPLIZNAHBYS@horizontherapeutics.com](mailto:UPLIZNAHBYS@horizontherapeutics.com)



Complete all required fields, including prescriber's signature and date, to initiate patient enrollment process. For support and/or assistance obtaining patient signature, call Horizon By Your Side at 1-833-842-8477. (\* or X Indicates a required field)

## PATIENT INFORMATION (\* or X Indicates a required field)

X First name\* \_\_\_\_\_ X Last name\* \_\_\_\_\_  
X Sex\*:  Male  Female \_\_\_\_\_ Date of birth\*: X \_\_\_\_\_  
(MM/DD/YYYY)  
Primary language \_\_\_\_\_ Email address \_\_\_\_\_  
X Primary telephone\* \_\_\_\_\_ Consent to leave voice message at patient and/or alternative contact telephone?  Yes  No  
 Home  Cell \_\_\_\_\_ Consent to send text message?  Yes  No  
X Address\* \_\_\_\_\_  
X City\* \_\_\_\_\_ X State\* \_\_\_\_\_ X ZIP Code\* \_\_\_\_\_  
Alternative contact \_\_\_\_\_ Alternative contact telephone \_\_\_\_\_

## DIAGNOSIS (\* or X Indicates a required field) (Required for benefits investigation)

X Diagnosis\*:  G36.0 - Neuromyelitis optica [Devic] \_\_\_\_\_ Date of diagnosis: \_\_\_\_\_  
(MM/DD/YYYY)  
X Has the patient ever tested positive for AQP4 antibodies?\*:  Yes  No  
Check all previous NMOSD therapies:  
 None/new diagnosis  Satralizumab-mwge  Riabni  
 Tocilizumab  Eculizumab  Ruxience  
 Steroid  Rituxan  Truxima  
 Other: \_\_\_\_\_

## INSURANCE INFORMATION (\* or X Indicates a required field) (Please include front and back copies of insurance card(s) with this form)

X Primary insurance\* \_\_\_\_\_ Secondary insurance \_\_\_\_\_  
X Policy #\* \_\_\_\_\_ Policy # \_\_\_\_\_  
X Policyholder's first and last name\* \_\_\_\_\_ Policyholder's first and last name \_\_\_\_\_  
X Insurance company telephone\* \_\_\_\_\_ Insurance company telephone \_\_\_\_\_  
X Group #\* \_\_\_\_\_ Group # \_\_\_\_\_  
X Policyholder's DOB\*: \_\_\_\_\_ Policyholder's DOB: \_\_\_\_\_  
(MM/DD/YYYY) (MM/DD/YYYY)  
 UNINSURED: Patient is uninsured to my knowledge.

## PATIENT AUTHORIZATION (Please see authorization language on page 2)

X Patient signature\* \_\_\_\_\_ Date\*: X \_\_\_\_\_  
Please read page 2 (MM/DD/YYYY)  
X Printed full name\* \_\_\_\_\_

Please include page 2 with the Patient Enrollment Form submission.  
Please see Important Safety Information on page 2 and see accompanying Full Prescribing Information or visit [UPLIZNAhcp.com](http://UPLIZNAhcp.com).

## PRESCRIBER INFORMATION (\* or X Indicates a required field)

X First name\* \_\_\_\_\_ X Last name\* \_\_\_\_\_  
X Address\* \_\_\_\_\_  
X City\* \_\_\_\_\_ X State\* \_\_\_\_\_ X ZIP Code\* \_\_\_\_\_  
X NPI #\* \_\_\_\_\_ X Tax ID #\* \_\_\_\_\_ X State license #\* \_\_\_\_\_  
Clinic/hospital affiliation \_\_\_\_\_  
Office contact name \_\_\_\_\_  
X Office contact telephone\* \_\_\_\_\_ X Fax\* \_\_\_\_\_  
Email address \_\_\_\_\_  
Preferred communication:  Telephone  Email  
Prescriber specialty: \_\_\_\_\_

## INFUSION FACILITY

Do you have a preferred infusion facility?  Yes  No If yes, please provide the preferred infusion facility information below. If no, Horizon By Your Side will provide options for your patient.  
Facility name \_\_\_\_\_  
Facility address \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ ZIP Code \_\_\_\_\_  
Telephone \_\_\_\_\_ Fax \_\_\_\_\_  
Facility NPI # \_\_\_\_\_ Facility tax ID # \_\_\_\_\_

## PRESCRIPTION INFORMATION (Required for specialty pharmacy)

Prescription Information: UPLIZNA® (inebilizumab-cdon) ICD-10 code: G36.0  
NDC: 75987-150-03: One carton containing three 100 mg/10 mL vials  
Dose: 300 mg per IV infusion Target infusion date: \_\_\_\_\_  
(MM/DD/YYYY)  
Initial Rx:  300 mg IV infusion over 90 minutes at Day 1 and 2 weeks later  
Maintenance Rx:  300 mg IV infusion over 90 minutes every 6 months Refill: \_\_\_\_\_ times  
 Patient is Medically Urgent: Medically Urgent means a patient who (1) is at risk of permanent disability from either an NMOSD medical crisis or potential attack; (2) is either: (i) not on an NMOSD maintenance therapy OR (ii) on an alternate maintenance therapy; and (3) requires accelerated treatment with UPLIZNA because a viable insurance access pathway is not available prior to the proposed first infusion date, resulting in a delay in receiving treatment. I certify that the treatment of the Patient is Medically Urgent per the definition above, requiring accelerated access to UPLIZNA.  
Administration instructions: Dilute 300 mg (30 mL) in 250 mL 0.9% Sodium Chloride Injection and administer diluted infusion over approximately 90 minutes at an increasing rate: 42 mL/hour for first 30 minutes, followed by 125 mL/hour for the next 30 minutes, then 333 mL/hour until completion.  
State requirements: The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc.  
Noncompliance with state-specific requirements could result in outreach to the prescriber.

## PRESCRIBER CERTIFICATION (Please see certification language on page 2)

X Prescriber signature/Dispense as written\* \_\_\_\_\_ Substitutions allowed \_\_\_\_\_  
Written or e-signature only; stamps not acceptable.  
Date\*: X \_\_\_\_\_  
(MM/DD/YYYY)  
The above signature grants permission to share records with the co-management team and infusion facility.  
X  I certify that the above therapy is medically necessary for the treatment of neuromyelitis optica spectrum disorder (NMOSD).\*  
I authorize Horizon Therapeutics USA, Inc. and its affiliates and their respective employees or agents (collectively, "Horizon") to transmit the above prescription by any means allowed under applicable law to the appropriate specialty pharmacy for my patient.

I certify that the above therapy is medically necessary, that the information provided is accurate to the best of my knowledge and that my patient is being administered UPLIZNA® (inebilizumab-cdon) injection, 300 mg, for intravenous infusion in accordance with the labeled use of the product. I understand that Horizon Therapeutics USA, Inc. and its affiliates and their respective employees or agents (collectively, "Horizon") will use this information to administer the Horizon By Your Side program (the "Program"), which provides a wide array of patient-focused services, including providing logistical and non-medical treatment support for UPLIZNA, as prescribed, and educating about the insurance process. I authorize these parties to act on my behalf for the limited purposes of transmitting this prescription by facsimile to the appropriate pharmacy designated by the patient utilizing their benefit plan. By my signature, I also certify that (1) my patient or his/her personal representative has provided a signed HIPAA authorization that allows me to share protected health information with Horizon for purposes of the Program and (2) I have obtained the patient's authorization to release such information as may be required for AllCare Plus Pharmacy (or another party acting on behalf of Horizon) to assess insurance coverage for UPLIZNA and assistance in initiating or continuing UPLIZNA as prescribed. I further understand and agree that (a) any medication or service provided through the Program as a result of this form is for the named patient only and is not being made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use UPLIZNA or any other Horizon product or service, for any other person; (b) my decision to prescribe UPLIZNA was based solely on my professional determination of medical necessity; and (c) I will not seek reimbursement for any medication or service provided by or through the Program from any government program or third-party insurer. I understand that Horizon may modify or terminate the Program at any time without notice. The completion and submission of coverage- or reimbursement-related documentation are the responsibility of the patient and healthcare provider. Horizon makes no representation or guarantee concerning coverage or reimbursement for any item or service. On behalf of the patient, Horizon expects the prescriber to coordinate with Horizon By Your Side to provide, to the best of the prescriber's ability, in-network infusion services and work with Horizon By Your Side to effectively communicate both in-network and out-of-network choices and the corresponding financial obligations of the patient connected to each choice. Should the prescriber knowingly perform out-of-network services without the knowledge and consent of the patient, the prescriber cannot balance bill the patient for the out-of-network services.

By filling out and signing this form, the enrollment process in Horizon By Your Side has initiated; however, your patient must sign a Patient Authorization to complete enrollment in Horizon By Your Side. Please note that your patient will not benefit from the services and support offered by the Program unless your patient signs a Patient Authorization, consenting to receiving such services. If your patient does not sign the Patient Authorization contained within this form, Horizon will contact the patient to determine whether the patient is interested in signing a separate Patient Authorization.

**Medically Urgent Attestation**

If the "Patient is Medically Urgent" box has been checked, I further understand and agree that (a) my decision to certify that the Patient with UPLIZNA is Medically Urgent, requiring accelerated access to therapy, was based solely on my professional determination; (b) I am actively pursuing insurance coverage for UPLIZNA for the Patient; and (c) I will not seek reimbursement, including from any government program, third-party insurer or the Patient for UPLIZNA provided by Horizon. I understand that Horizon will use information provided by me or my representatives to administer the Program and provide free UPLIZNA for the Patient.

**PATIENT CONSENT FOR PATIENT INFORMATION, ENROLLING IN SERVICES, AND ACCESSING FINANCIAL SUPPORT (REFERRED TO AS "PATIENT AUTHORIZATION")**

I hereby authorize my healthcare providers, my health insurance carriers, and my pharmacies to use and disclose my individually identifiable health information, including my medical records, insurance coverage information, and my name, address, and telephone number to Horizon Therapeutics USA, Inc. and its affiliates and their respective agents and representatives (collectively, "Horizon"), including third parties authorized by Horizon to administer drug support and to dispense drugs (collectively, "Horizon By Your Side") for the following purposes: (1) to establish eligibility for benefits; (2) to communicate with my healthcare providers and me about my treatment or condition and related products; (3) to facilitate the provision of products, supplies, or services by a third party including, but not limited to, specialty pharmacies; (4) to register me in any applicable product registration program required for my treatment; (5) to enroll me in eligible patient support programs offered by Horizon By Your Side and/or Horizon, including nursing or patient access support services (government-reimbursed programs may not be eligible for all support services offered; please contact Horizon By Your Side for determination); and (6) to send me marketing information or offer me products and services related to my treatment or condition (or other products or services in which I might be interested) and to contact me occasionally to obtain my feedback (for market research purposes only) about my treatment, my condition, or my experience with Horizon and/or Horizon By Your Side otherwise as required or permitted by law. Further, I appoint the Program, on my behalf, to proceed with Program services and to convey this prescription to the dispensing pharmacy, to the extent permitted under state law. I understand the pharmacies may receive a fee from Horizon in exchange for (1) providing me with certain materials and information described above, and (2) using or disclosing certain health information pursuant to this Authorization.

I understand that Horizon, as well as my healthcare providers, cannot require me, as a condition of having access to medications, prescription drugs, treatment, or other care, to sign this Authorization. I understand that I am entitled to a copy of this Authorization.

I understand that information disclosed pursuant to this Authorization in some cases may be redisclosed by the recipient and no longer protected by HIPAA or other privacy laws. But Horizon has agreed to use and disclose my information only for purposes of operating the Program. I understand that I may cancel this Authorization at any time by mailing a signed letter requesting such cancellation to Horizon By Your Side, 1 Horizon Way, Deerfield, IL 60015, but that this cancellation will not apply to any information used or disclosed by my healthcare providers and/or health insurance carriers based on this Authorization before they are notified that I have canceled it. Unless required by state law, this Authorization is valid for whichever is greater: (a) the duration remaining on this treatment or (b) 10 years from the date signed above. A photocopy of this Authorization will be treated in the same manner as the original.

**INDICATION AND IMPORTANT SAFETY INFORMATION**

**INDICATION**

UPLIZNA (inebilizumab-cdon) is indicated for the treatment of neuromyelitis optica spectrum disorder (NMO) 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.

**Please see accompanying Full Prescribing Information or visit UPLIZNAhcp.com.**



## UPLIZNA MEDICATION ORDER

Patient's Name (Last, First, Middle) \_\_\_\_\_ DOB \_\_\_\_\_

Patient's height in feet and inches \_\_\_\_\_ Patient's weight in pounds \_\_\_\_\_

### ■ Diagnosis

G36.0 Neuromyelitis Optica

### ■ Details Needed for Approval

- Medical records including detailed documentation of NMOSD clinical characteristics.
- Hepatitis B surface antigen and Hepatitis B core total antibody results from the past two months.
- Negative TB test (QFT, PPT or Spot TB) from the past two months.
- Serum immunoglobulin levels and AQP4 positive antibody lab results.
- Will the patient be using Uplizna with complement-inhibitor (ie. Exulizumab), anti-CD-20-directed antibody (ie. Rituximab) therapy, or sataralizumab-mwge (Enspryng)? \_\_\_\_\_
- Will the patient concurrently be under treatment for multiple sclerosis? \_\_\_\_\_
- Will the patient concurrently be treated with complement inhibitors (such as Soliris) ? \_\_\_\_\_
- Will the patient concurrently be treated with Anti-IL6 therapy (such as Actemra) ? \_\_\_\_\_
- Does the patient have a history of reaction or intolerance to Ritixumab? \_\_\_\_\_ If yes, please provide a written opinion from the prescriber that the same reaction or intolerance would not be expected to occur with Uplizna.
- If the patient has been on IVIG therapy when was the last treatment? \_\_\_\_\_
- How many episodes of relapse requiring rescue therapy has the patient had in the past two years? \_\_\_\_\_
- Please include the patient's EDSS score. (Usually a score of  $\leq 7.5$  is required by insurance carriers for approval.)

### ■ Premedication Order

Oral medications to be taken by the patient at least 60 minutes prior to start of infusion treatment. They may be taken by the patient at home.

Acetaminophen \_\_\_\_\_mg  Diphenhydramine \_\_\_\_\_mg

IV medications to be administered 30 minutes prior to start of the infusion treatment.

Methylprednisolone 80mg  Solu-Cortef 125mg

### ■ Uplizna (inebilizumab-cdon) Medication Order

Initial dose: 300mg Uplizna by IV, followed by 300mg Uplizna by IV two (2) weeks later, and a third dose of 300mg Uplizna by IV six (6) months after the second infusion.

Maintenance dose: 300mg Uplizna by IV every six (6) months for one (1) year, maximum two (2) treatments.

Medication to be handled per manufacturer directions. Dilute dose of 250ml of 0.9% sodium chloride IV bag and mix with gentle inversion. Infusion administered over approximately 90 minutes: 30 minutes at 42 ml/hr, then 30 minutes at 215 ml/hr, and finally increased to 333 ml/hr for the remainder. After infusion flush with normal saline. Check vitals and monitor for signs and symptoms of an infusion reaction at start, throughout infusion, and after completion. Patient to be monitored for at least one hour after the completion of the infusion.

### ■ Rescue Management in case of Infusion Therapy Reaction

These include fever, chills, rigors, headache, rash, itching, swelling, edema, nausea, vomiting, abdominal pain, hypotension, and respiratory distress.

- Stop medication infusion and start normal saline infusion at 50 ml/hr. Call ordering provider to report reaction.
- Follow standing reaction orders, including Diphenhydramine, Methylprednisolone, Albuterol and oxygen as needed.
- For severe reactions, administer Epi-pen or equivalent and call 911. Repeat if severe symptoms persist.

### ■ Ordering Provider Authorization

Provider Signature: \_\_\_\_\_ Name: \_\_\_\_\_ Date: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_ Indiv. NPI #: \_\_\_\_\_ License: \_\_\_\_\_

Best Contact Person in Office: \_\_\_\_\_ Direct Phone to Contact Person: \_\_\_\_\_

### ■ Documentation to Include:

- Patient demographics and insurance, including card scans (both medical and pharmacy benefit cards, both sides).
- Most recent chart notes and, if available, last history and physical. All relevant scans, tests and laboratory results.

**FAX THIS ORDER AND SUPPORTING DOCUMENTATION TO 201-266-0437 OR UPLOAD USING YOUR SECURE DEDICATED WEBPAGE – TO GET A PERSONAL LINK PLEASE CONTACT THE INTAKE TEAM.**