Beacon Infusion
Healthcare Services

Headquarters Location:
1075 Stephenson Ave, Suite D-2, Oceanport, NJ 07757
Telephone: (833) 223-2266 Fax: (732) 329-2322

UPLIZNA MEDICATION ORDER

Please complete all attached pages.

The two Horizon By Your Side forms should be submitted to Horizon Therapeutics via fax at 833-329-8477.

The last page, the Beacon Infusion order, should be accompanied by the required chart notes and lab results and submitted to Beacon Infusion via fax at 732-329-2322.

The forms should be as complete as possible. This will significantly ease the authorization process. Once the case is transferred to us by Horizon Therapeutics, we will be in touch with your office regarding next steps.

Thank you!

PATIENT ENROLLMENT FORM

Once complete, submit by fax **1-833-329-8477**
or email **UPLIZNAHBYS@horizontherapeutics.com**

HORIZON BY your side

UPLIZNA® inebilizumab-cdon

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.

(*Indicates a required field)

PATIENT INFORMATION

First name* _____ **Last name*** _____

Sex*: ◯ Male ◯ Female **Date of birth*:** _____ (MM/DD/YYYY)

Primary language _____ Email address _____

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

Address* _____

City* _____ **State*** _____ **ZIP Code*** _____

Alternative contact name _____ Alternative contact telephone _____

DIAGNOSIS
(Required for benefits investigation)

Diagnosis*: ◯ G36.0 - Neuromyelitis optica [Devic] **Date of Diagnosis:** _____ (MM/DD/YYYY)

Has the patient ever tested positive for AQP4 antibodies?*: ◯ Yes ◯ No

Check all previous NMOSD therapies:

◯ Oral immunosuppressant(s) (Mycophenolate Mofetil, Methotrexate, Azathioprine)
◯ Steroid
◯ Rituximab
◯ Satralizumab-mwge
◯ Eculizumab
◯ Tocilizumab
◯ None/new diagnosis
◯ Other: _____

INSURANCE INFORMATION
(Please include front and back copies of insurance card(s) with this form)

Primary insurance* _____ Secondary insurance _____

Policy #* _____ Policy # _____

Policyholder's first and last name* _____ Policyholder's first and last name _____

Insurance company telephone* _____ Insurance company telephone _____

Group #* _____ Group # _____

Policyholder's DOB*: _____ (MM/DD/YYYY) Policyholder's DOB: _____ (MM/DD/YYYY)

◯ UNINSURED: Patient is uninsured to my knowledge.

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.

Beacon Infusion Healthcare Services
Facility name

Whichever location is most convenient for the patient. Please visit www.beaconinfusion.com for sites.
Facility address

City _____ State _____ ZIP Code _____

(833) 223-2266
Telephone

(732) 329-2322
Fax

Facility NPI # _____ Facility tax ID # _____

PRESCRIBER INFORMATION

First name* _____ **Last name*** _____

Address* _____

City* _____ **State*** _____ **ZIP Code*** _____

NPI #* _____ **Tax ID #*** _____ **State license #*** _____

Clinic/hospital affiliation _____

Office contact name _____

Office contact telephone* _____ **Fax*** _____

Email address _____

Preferred communication: ◯ Telephone ◯ Email

Prescriber specialty: _____

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

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) requires accelerated treatment with UPLIZNA, (2) is experiencing a medical crisis or is at risk of attack and permanent disability; and (3) is either:
– Not on an NMOSD maintenance therapy OR
– On an alternate maintenance therapy

Type of premedication	Route of administration	Examples (or equivalent)	Administration time prior to UPLIZNA infusion
Corticosteroid	Intravenous	Methylprednisolone 80 mg to 125 mg	30 minutes
Antihistamine	Oral	Diphenhydramine 25 mg to 50 mg	30-60 minutes
Antipyretic	Oral	Acetaminophen 500 mg to 650 mg	30-60 minutes

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*: _____ (MM/DD/YYYY)

The above signature grants permission to share records with the co-management team and infusion facility.

◯ **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.

Prescriber Certification

Please read and provide signature in Prescriber Certification section on page 1

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. If the "Patient is Medically Urgent" box has been checked, I further certify that treatment of the patient with UPLIZNA is Medically Urgent, requiring accelerated therapy. 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. 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.

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.

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.

Patient Consent for Patient Information, Enrolling in Services, and Accessing Financial Support (referred to as "Patient Authorization")

Please read and provide signature in Patient Authorization section below

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 cancelled 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.

Patient Authorization

X			
Patient signature Please read above	**Printed full name**	**Date:** (MM/DD/YYYY)	**DOB:** (MM/DD/YYYY)

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.

For additional information on UPLIZNA, please see Full Prescribing Information at UPLIZNAhcp.com.

HORIZON

Beacon Infusion
Healthcare Services

Headquarters Location:
1075 Stephenson Ave, Suite D-2, Oceanport, NJ 07757
Telephone: (833) 223-2266 Fax: (732) 329-2322

UPLIZNA MEDICATION ORDER

Patient's Name (Last, First, Middle) _____ **DOB:** _____

■ Diagnosis

G36.0 Neuromyelitis optica

■ Details Needed for Authorization

Patient's height in ft/in: _____ Patient's weight in lbs: _____

- Hepatitis B surface antigen and Hepatitis B core total antibody results from the past two months.
- Negative TB test (QFT, PPD 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. eculizumab), anti-CD-20-directed antibody (ie. rituzimab) therapy, or sataralizumab-mwge (Enspryng)? _____
- Please include the patient's EDSS score. (Usually a score ≤7.5 is required.)

■ Premedication Order

Oral medications to be taken by the patient at 30-60 minutes prior to start of infusion treatment. May be taken at home:

☐ Acetaminophen 500mg
☐ Acetaminophen 650mg
☐ Diphenhydramine 25mg
☐ Diphenhydramine 50mg

IV medication to be administered 30 minutes prior to start of the infusion treatment:

☐ Methylprednisolone 125mg
☐ Methylprednisolone 80mg

■ Uplizna (inebilizumab-cdon) 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 6 months for 1 year.

Medication to be handled per manufacturer directions. Dilute dose in 250ml of 0.9% sodium chloride IV bag and mix with gentle inversion. Infusion administered over approximately 90 minutes: 30 minutes at 42 ml/hour, then 30 minutes at 215 ml/hour, and finally increased to 333 ml/hour for the remainder. Post 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 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's Signature: _____ Name: _____ Date: _____

Address: _____

Phone: _____ Fax: _____ NPI #: _____ License: _____

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.
- Chart notes which include decision to begin treatment with Uplizna, including other prior administered therapies.

Fax this order and supporting documentation to (732) 329-2322.