Palmetto INFUSION®

Phone: 1-800-809-1265 Fax: 1-866-872-8920

Referral Status:		MRN:
☐ New referral	☐ Order change	☐ Order Renewal
Patient preferred clinic:		

Uplizna™ (inebilizumab-cdon) Standard Plan of Treatment

PATIENT DEMOGRAPHICS:

Date of Referral:		Patient's Phone:			
Patient Name:		Address:			
Date of Birth:		City, State, Zip:			
Height in inches:	Weight: LB or KG	Gender:	Allergies:	☐ See list	☐ NKDA

DIAGNOSIS: (PLEASE COMPLETE 2ND AND 3RD DIGITS TO COMPLETE ICD 10 FOR BILLING)

☐	G36.0 - Neuromyelitis Optica
☐	_____- Other:_____

REQUESTED DOCUMENTATION:		PREVIOUS ADMINISTRATION: HAS THIS PATIENT TAKEN THIS MEDICATION BEFORE?	
1	Insurance information	IF NO:	IF YES:
2	Most recent History & Physical	PLEASE STATE REQUIRED WASHOUT FROM PREVIOUS THERAPY:	LAST INFUSION DATE:
3	Full medication list		NEXT INFUSION DATE:
4	Tried and failed therapies		**IF ORDER CHANGE:**
5	**REQUIRED:** Hepatitis B panel for new start patients		☐ **Continue current order until insurance approved**
6	**REQUIRED:** TB screening for new start patients		

MEDICATION ORDERS:

NOTE: Patient may be ineligible to receive inebilizuman-cdon if receiving antibiotics for active infectious process, antifungal therapy, active fever and/or suspected infection, new onset or deterioration neurological changes, and/or surgery.

PREMEDICATION TO BE ADMINISTERED 30 MINUTES PRIOR TO ADMNISTRATION AS SELECTED

FDA labeling suggests premedication with antihistamine, antipyretic and IV corticosteroid

IV	Diphenhydramine	☐ 25mg	☐ 50mg						
	Methylprednisolone	☐ 40mg	☐ 125mg	☐ Other:					
	Famotidine	☐ 20mg	☐ 40 mg						
	Other:	☐							
PO	Acetaminophen	☐ 325mg	☐ 500mg	☐ 650mg	☐ 1000mg				
	Famotidine	☐ 20mg	☐ 40mg						
	Diphenhydramine	☐ 25mg	☐ 50mg						
	Fexofenadine	☐ 60mg	☐ 180mg						
	Cetirizine	☐ 10mg							
	Loratadine	☐ 10mg							
	Other:	☐							

MEDICATION/DOSE:

☑ Uplizna™ 300 mg IV to infuse over approximately 90 minutes per step protocol

Monitor patient for 1 hour post infusion completion.

FREQUENCY:

☐ Induction: Uplizna™ 300 mg IV at week 0 and week 2

☐ Maintenance: Uplizna™ 300 mg IV every 6 months (24 weeks) starting 6 months from week 0 dose

☐ Other: _____

SPECIAL/LAB ORDERS:

☐ _____

_____

Prescriber to monitor patient for symptoms of HBV and TB infection and reactivation as clinically appropriate.

☑ Refills x 12 months unless noted otherwise here:

LINE USE/CARE ORDERS:

☑ Start PIV/Access CVC

☑ Flush device per facility standard flushing procedure

ADVERSE REACTION & ANAPHYLAXIS ORDERS:

Administer acute infusion and anaphylaxis medications per Palmetto Infusion standing adverse reaction orders, which can be found at our website or scan here.

PRESCRIBER INFORMATION:

PROVIDER NAME:	PHONE:
ADDRESS:	FAX:
CITY, STATE, ZIP:	NPI:

PRESCRIBER SIGNATURE: (No stamp signatures)		DATE:
Dispense as written/Brand medically necessary	Substitution permitted	

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. (* 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 #

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

◯ UNINSURED: Patient is uninsured to my knowledge.

PATIENT AUTHORIZATION (Please see authorization language on page 2)

X **Patient signature*** Please read page 2 | **Date*:** X (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.

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.

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. 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")

Please read and provide signature in Patient Authorization section on page 1

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 (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.

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