INFUSION ORDER

Note: This form is being provided as a guide. Prescribers should use their clinical judgment when completing. Some facilities prefer to use their own infusion order forms. Check with your patient's facility before writing your infusion order.

PATIENT INFORMATION

Patient name:	**DOB:**	**Sex:** ☐ **M** ☐ **F**	**Weight:** kg
Phone number:	**Email:**		
Diagnosis: Neuromyelitis optica spectrum disorder		**ICD-10-CM code:** G36.0	
Emergency contact name:	**Phone number:**		

PHYSICIAN INFORMATION

Prescribing physician name:	**Practice name:**
Phone number:	**Fax number:**
Email:	**Office contact:**
Co-managing physician name:	**Phone number/email:**

REQUIREMENTS

Please attach: 1. List of current medications, 2. Copy of the patient's insurance card, 3. Clinical progress notes, history and physical (H&P) to support diagnosis, and 4. Relevant labs.

Prescriber must indicate that all of the following requirements have been met (attach supporting documentation):

☐ Quantitative immunoglobulins **within normal limits**

☐ Anti-aquaporin-4 (AQP4) **antibody positive *(required)***

☐ Latent TB screening **negative**

☐ HBV screening **negative**

If any of the above are *not* checked, attach treatment/consultation notes clearing the patient for inebilizumab-cdon therapy

PREINFUSION

☐ **Assess for contraindications; hold infusion and notify provider for:**

- signs/symptoms of active infection;
- planned or recent invasive/surgical procedure;
- receipt of live or live-attenuated vaccines within 4 weeks;
- chance of pregnancy; or
- signs/symptoms of PML (new or worsening unilateral weakness, confusion or changes in vision, thinking, memory, balance, or personality/mood)

☐ **Obtain vital signs at baseline and with rate changes**

☐ **Establish vascular access**

☐ **If infusion-related reaction occurs, stop infusion and treat per orders/protocol as clinically indicated**

PREMEDICATIONS

Administer the following premedications prior to each infusion of UPLIZNA to reduce infusion reactions.
Prescriber must select *one* option within each set of brackets for each medication:

☐ Acetaminophen	[☐ **500 mg** ☐ **650 mg**]	☐ **PO**	once [☐ **30** ☐ **60**] min prior to infusion
☐ Methylprednisolone	[☐ **80 mg** ☐ **125 mg** ☐ _____ **mg**]	☐ **IV**	once [☐ **30** ☐ **60**] min prior to infusion
☐ Diphenhydramine	[☐ **25 mg** ☐ **50 mg** ☐ _____ **mg**]	☐ **PO**	once [☐ **30** ☐ **60**] min prior to infusion

MEDICATION ORDER

Dilute inebilizumab-cdon 300 mg/30 mL in 250 mL 0.9% sodium chloride and administer intravenously using a sterile, low-protein binding 0.2- or 0.22-micron in-line filter using rates in the table below.

Preparation: Transfer 30 mL of UPLIZNA (10 mL from 3 vials) into an intravenous bag containing 250 mL of 0.9% Sodium Chloride Solution, USP. Mix by gentle inversion. Do not shake. Prepared infusion solution should be at room temperature.

Frequency:

☐ On Day 1 and Day 15; repeat in 6 months (from Day 1)

☐ Every 6 months (date of last treatment:_____)

Administration: Intravenous via an infusion pump at an increasing rate to completion at approximately 90 minutes. Follow the schedule in the table below:

Recommended Infusion Rate for UPLIZNA Administration When Diluted in a 250-mL Intravenous Bag

Elapsed Time (minutes)	Infusion Rate (mL/hour)
0-30	42
31-60	125
61 to completion	333

Monitor closely for infusion reactions during and for at least 1 hour after completion of the infusion.

Post Infusion:

☐ Flush administration set with 0.9% sodium chloride to deliver residual volume

☐ Record vital signs immediately following infusion and prior to discharge

☐ Leave IV in place for observation period; remove prior to discharge

☐ Monitor patient for hypersensitivity reaction for a period of 60 minutes following infusion

☐ Provide patient with discharge instructions

IMPORTANT NOTES

☐ Administer UPLIZNA under the close supervision of an experienced healthcare professional with access to appropriate medical support to manage serious infusion reactions

☐ For life-threatening infusion reactions, immediately and permanently stop UPLIZNA and administer appropriate supportive treatment. For less severe infusion reactions, management may involve temporarily stopping the infusion, reducing the infusion rate, and/or administering symptomatic treatment

☐ Share post-infusion chart notes with the prescriber

☐ Other notes:_____

Physician signature:_____ **Date:**_____

If using this as an order form, you must fill out with signature and date.

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.