

INFUSION ORDER

Note: This form is being provided as a guide. Prescribers should use their clinical judgment when completing, including determining the appropriate coding (some sample codes provided). 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:		
Emergency contact name:	Phone number:		
Diagnosis (potential codes are listed below):*			
NMOSD: G36.0, neuromyelitis optica in adult patients (Devic); Aquaporin-4 (AQP4) antibody positive (required)	IgG4-RD: D89.84, immunoglobulin G4-related disease in adult patients Other (specify ICD-10 code): _____ Please provide secondary ICD-10 code, if applicable: _____		
<small>*A copy of this information can be given to the patient to bring to his/her appointment. The sample diagnosis codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for UPLIZNA®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered FDA-approved indications for UPLIZNA®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.</small>			
REQUIREMENTS: (Assessments prior to first dose of UPLIZNA)			
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 typically must indicate that all of the following requirements have been met (attach supporting documentation):			
Hepatitis B virus screening negative	Active/latent TB screening negative	Quantitative serum immunoglobulins within normal limits	Administer immunizations per guidelines ≥4 weeks prior to initiation of UPLIZNA
If any of the above are <i>not</i> checked, attach treatment/consultation notes clearing the patient for inebilizumab-cdon therapy			
PHYSICIAN INFORMATION			
Prescribing physician name:	Practice name:		
Phone number:	Fax number:		
Email:	Office contact:		
Co-managing physician name:	Phone number/email:		
PREINFUSION			
Assess for contraindications; hold infusion and notify provider for:			
<ul style="list-style-type: none">signs/symptoms of active infection;planned or recent invasive/surgical procedure;receipt of live or live-attenuated vaccines within 4 weeks;	<ul style="list-style-type: none">chance of pregnancy; orsigns/symptoms of progressive multifocal leukoencephalopathy (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			
Please see the full Prescribing Information for additional Important Dosing and Administration information.			

INDICATIONS

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.

UPLIZNA® is indicated for the treatment of Immunoglobulin G4-related disease (IgG4-RD) in adult patients.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

UPLIZNA® (inebilizumab-cdon) is contraindicated in patients with a history of a life-threatening infusion reaction to UPLIZNA, active hepatitis B infection, or active or untreated latent tuberculosis.

Please see additional Important Safety Information throughout and UPLIZNA® [full Prescribing Information](#) at UPLIZNAhcp.com.



Patient Name: _____

PREMEDICATIONS

Administer the following premedications prior to each infusion of UPLIZNA to reduce infusion reactions. Prescriber must indicate dosage for each medication selected:

Type of Premedication	Route of Administration	Examples (or Equivalent)	Administration Time Prior to UPLIZNA Infusion
corticosteroid	intravenous	methylprednisolone 80 mg to 125 mg: _____ mg	30 minutes
antihistamine	oral	diphenhydramine 25 mg to 50 mg: _____ mg	30 to 60 minutes
antipyretic	oral	acetaminophen 500 mg to 650 mg: _____ mg	30 to 60 minutes

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:

Initial dose: On day 1 and day 15;
repeat in 6 months (from day 1)

Subsequent doses: 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.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

- Infusion Reactions:** Can cause infusion reactions, including anaphylaxis. Symptoms can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash, or palpitations. During the randomized clinical trial period (RCP), infusion reactions were observed with the first course of UPLIZNA in 9.3% of NMOSD patients. Infusion reactions of UPLIZNA were observed in 7.4% of IgG4-RD patients during the RCP. 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 antipyretic. 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.

- Infections:** An increased risk of infections has been observed with other B-cell depleting therapies. The most common infections reported by UPLIZNA-treated patients in the NMOSD RCP and open-label clinical trial periods were urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%), and influenza (7%). In the IgG4-RD RCP and open-label period, the most common infections reported by UPLIZNA-treated patients were upper respiratory tract infection (11%), nasopharyngitis (10%), urinary tract infection (9%), and influenza (6%). Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

Please see additional Important Safety Information throughout and UPLIZNA® [full Prescribing Information](#) at [UPLIZNAhcp.com](#).



Patient Name: _____

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 postinfusion chart notes with the prescriber

Other notes:

Please see Important Safety Information throughout and the UPLIZNA full Prescribing Information for additional adverse event considerations and important Dosing and Administration information.

Physician signature: _____ Date: _____

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

• Infections (cont'd):

Possible Increased Risk of Immunosuppressant Effects with Other Immunosuppressants: UPLIZNA has not been studied in combination with other immunosuppressants. If combining UPLIZNA with another immunosuppressive therapy, consider the potential for increased immunosuppressive effects.

Hepatitis B Virus (HBV) Reactivation: Risk of HBV reactivation has been observed with other B-cell depleting antibodies. There have been no cases of HBV reactivation in patients treated with UPLIZNA, but patients with chronic HBV infection were excluded from clinical trials. Perform HBV screening in all patients before initiation of treatment. Do not administer to patients with active hepatitis. For patients who are chronic carriers of HBV [HBsAg+], consult liver disease experts before starting and during treatment.

Progressive Multifocal Leukoencephalopathy (PML): Although no confirmed cases of 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. In UPLIZNA clinical trials one subject died following the development of new brain lesions for which a definitive diagnosis could not be established, though the differential diagnosis included an atypical NMOSD relapse, PML, or acute disseminated encephalomyelitis. At the first sign or symptom suggestive of PML, withhold UPLIZNA and perform an appropriate diagnostic evaluation. MRI findings may be apparent before clinical signs or symptoms. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

Tuberculosis

Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating UPLIZNA. Consider anti-tuberculosis therapy prior to initiation of UPLIZNA in patients with a history of latent active tuberculosis in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent tuberculosis but having risk factors for tuberculosis infection. Consult infectious disease experts regarding whether initiating anti-tuberculosis therapy is appropriate before starting treatment.

Please see additional Important Safety Information throughout and UPLIZNA® [full Prescribing Information](#) at [UPLIZNAhcp.com](#).



IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

• Infections (cont'd):

Vaccinations

Administer all immunizations according to immunization guidelines at least 4 weeks prior to initiation of UPLIZNA. The safety of immunization with live or live-attenuated vaccines following UPLIZNA therapy has not been studied, and vaccination with live-attenuated or live vaccines is not recommended during treatment and until B-cell repletion.

Vaccination of Infants Born to Mothers Treated with UPLIZNA During Pregnancy

In infants of mothers exposed to UPLIZNA during pregnancy, do not administer live or live-attenuated vaccines before confirming recovery of B-cell counts in the infant. Depletion of B-cells in these exposed infants may increase the risks from live or live-attenuated vaccines. Non-live vaccines, as indicated, may be administered prior to recovery from B-cell and immunoglobulin level depletion, but consultation with a qualified specialist should be considered to assess whether a protective immune response was mounted.

- **Reductions 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 levels of quantitative serum immunoglobulins during treatment with UPLIZNA, especially in patients with opportunistic or recurrent infections, and until B-cell repletion after discontinuation of therapy. Consider discontinuing UPLIZNA therapy if a patient with low immunoglobulin G or M develops a serious opportunistic infection or recurrent infections, or if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.
- **Fetal Risk:** Based on animal data, UPLIZNA can cause fetal harm due to B-cell lymphopenia and reduce antibody response in offspring exposed to UPLIZNA even after B-cell repletion. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other B-cell depleting antibodies during pregnancy. Advise females of reproductive potential to use effective contraception while receiving UPLIZNA and for at least 6 months after the last dose.

ADVERSE REACTIONS

- The most common adverse reactions in NMOSD (at least 10% of patients treated with UPLIZNA and greater than placebo) were urinary tract infection and arthralgia.
- The most common adverse reactions in IgG4-RD (at least 10% of patients treated with UPLIZNA and greater than placebo) were urinary tract infections and lymphopenia.

Please see UPLIZNA® [full Prescribing Information](https://www.uplizna.com) at [UPLIZNAhcp.com](https://www.uplizna.com).