

Administering UPLIZNA: Site of care options to meet patient needs



Hospital Outpatient
Department



Physician Office
Infusion Suite



Independent
Infusion Center



Home
Infusion

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.

Please see additional Important Safety Information on back cover and [Full Prescribing Information](https://www.uplizna.com) at [UPLIZNAhcp.com](https://www.uplizna.com).

UPLIZNA[®]
inebilizumab-cdon



An infusion setting should meet your patients' needs

Each site of care (SOC) has unique features that may help you decide the best option for your patients. Some payors may require that a specific SOC be used in order for a service to be covered.



Site of Care	 Hospital Outpatient Department	 Physician Office Infusion Suite	 Independent Infusion Center	 Home Infusion
Overview	Facilities established as part of the hospital for patients who do not need to be admitted to the hospital to receive their infusions.	Infusion may take place either in the office of the prescribing HCP or in the office of another HCP with established infusion capabilities.	Infusion centers established separately from and not owned by the hospital or physician office. These sites are staffed by nurses and may or may not have physicians on site for patient care.	Trained nursing staff can provide infusion services in the patient's home, whether for convenience or necessity. Home infusion teams can provide their own supplies, coordinate scheduling, and handle monitoring.
Benefits	<ul style="list-style-type: none"> • Provides physician oversight • Highly experienced with administering IV infusions • Patients might feel like the hospital is the best location with the most trained staff • Additional resources might be available from the hospital (billing, scheduling, patient education) 	<ul style="list-style-type: none"> • Provides physician oversight • Highly experienced with administering IV infusions • Patients may be more comfortable in their HCP's office than in a new facility • Allows for easier tracking and communication of lab test results 	<ul style="list-style-type: none"> • Provides professional oversight • Highly experienced with IV infusions • Often have more modern amenities since infusion is their business (nicer chairs, TVs, WiFi) • May have more capacity or scheduling capabilities given infusion-only focus 	<ul style="list-style-type: none"> • Provides professional oversight • May offer convenience for patients • Highly experienced with administering IV infusions • Opportunity for infusion education with home infusion nurse • Patients can stay in the comfort of their own home • Allows patients to remain adherent to treatment when they have to stay home
Considerations	<ul style="list-style-type: none"> • UPLIZNA may need to be on the hospital formulary in order to be infused • May be scheduling delays due to high volume of other specialty infusions 	<ul style="list-style-type: none"> • If selecting another provider to be responsible for infusions, initial office visit may be required for patients • Not all offices are set up with infusion capabilities; the closest office with infusion capabilities for the patient could be too far • Not all specialist offices with infusion capabilities are willing to take on patients for infusion-only services and may only agree to infuse under a co-management arrangement 	<ul style="list-style-type: none"> • May not have a physician on site, which may not meet Medicare requirements • Patients may not be comfortable without a physician present 	<ul style="list-style-type: none"> • No physician on site, which may not meet Medicare requirements • Insurance requirements may prefer in-home infusion, or may not cover it, depending on the plan • Patients may not feel comfortable letting providers into their home • Hospitals or independent infusion centers may also have home infusion capabilities



Support for offices that do not have infusion capabilities

Third-party infusion management organizations perform and manage infusions that occur in an HCP office. These organizations provide resources and support that is unique for each office based on contracted services.

*A patient signature of consent is required in accordance with HIPAA to complete enrollment in Amgen By Your Side, a patient support program. HCP, healthcare professional; HIPAA, Health Insurance Portability and Accountability Act; IV, intravenous.

Please see Important Safety Information on back cover and [Full Prescribing Information](#) at [UPLIZNAhcp.com](#).

For more education on the SOC options available to patients prescribed an Amgen infused medicine, contact Amgen By Your Side, a patient support program.



Amgen By Your Side is a support program for patients prescribed UPLIZNA. Our dedicated team is your patient's partner, committed to providing nonmedical support to help patients as they start and continue on treatment as prescribed.

Call **1-844-469-4297** or visit www.AmgenByYourSide.com to initiate enrollment for your patient by submitting the Patient Enrollment Form.*

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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 [Full Prescribing Information](#) at [UPLIZNAhcp.com](#).