

UPLIZNA

Key Product Features



INDICATIONS

UPLIZNA® (inebilizumab-cdon) is indicated in adult patients for the treatment of: anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD); Immunoglobulin G4-related disease (IgG4-RD); anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive (Ab+) generalized myasthenia gravis (gMG).

Recommended dosing¹	<p>UPLIZNA is administered as an intravenous infusion. The recommended dosage is:</p> <ul style="list-style-type: none"> • Initial dose: 300-mg intravenous infusion followed 2 weeks later by a second 300-mg intravenous infusion • Subsequent doses (starting 6 months from the first infusion): single 300-mg intravenous infusion every 6 months <p>Please see the full Prescribing Information for additional important information on assessments required prior to the first dose of UPLIZNA and administration information.</p>
NDC number¹	<p>10-digit: 75987-150-03 11-digit: 75987-0150-03</p>
Storage & handling¹	<ul style="list-style-type: none"> • Refrigerate at 36°F to 46°F (2°C to 8°C) in original carton to protect from light • Do not freeze • Do not shake • Store vials upright
Product expiration	<p>The expiration date is printed on each dispensing pack and vial label</p>
Product returns	<p>For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-800-28-AMGEN (1-800-282-6436). Credit for returns is subject to Amgen's current Product Return Policy</p>

NDC, National Drug Code.

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 on pages 3-4 and UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).



UPLIZNA Key Product Features (cont'd)

Packaging¹	Each carton contains three 100 mg/10 mL single-dose vials Description: UPLIZNA is a clear to slightly opalescent, colorless to slightly yellow solution	
Dimensions	1 carton: 93 × 39 × 150 mm	
Weight	1 complete carton (3 vials per carton): 0.5 lbs	
ICD-10-CM codes*	NMOSD: G36.0	Description: Neuromyelitis optica (Devic)
	IgG4-RD: D89.84	Description: Immunoglobulin G4-related disease
	gMG: G70.00 [†]	Description: Myasthenia gravis without (acute) exacerbation
	gMG: G70.01 [†]	Description: Myasthenia gravis with (acute) exacerbation
HCPCS code*	Code: J1823	Description: Injection, inebilizumab-cdon, 1 mg
Ordering information	Specialty pharmacy contact information: Accredo Health Group, Inc: 1-800-803-2523	
	Specialty distributors contact information	
	Physician Channel (independent physicians and clinics) BioCareSD®: 1-800-304-3064 CuraScript SD®: 1-877-599-7748 McKesson Specialty Health: 1-855-477-9800 Metro® Medical: 1-800-768-2002 Cardinal Health™ Specialty Pharmaceutical Distribution: 1-866-476-1340 M&D Specialty Distribution: 1-800-388-3833 Oncology Supply®: 1-800-633-7555 Besse® Medical: 1-800-543-2111	
Acute Channel (hospitals and non-retail pharmacies) BioCareSD® Acute: 1-800-304-3064 McKesson Plasma and Biologics: 1-877-625-2566 M&D Specialty Distribution: 1-800-388-3833 Cardinal Health™ Specialty Pharmaceutical Distribution: 1-866-476-1340 ASD Healthcare®: 1-800-746-6273		

*These codes are not all-inclusive. Appropriate codes vary by patient, payers, and setting for care. Correct coding is the responsibility of the provider submitting the claim. Amgen does not make any representation or guarantee for reimbursement or coverage.

[†]Other potential codes relevant to generalized myasthenia gravis include: G70 (Category: Myasthenia gravis and other myoneural disorders); G70.0 (Category: Generalized myasthenia gravis). Healthcare professionals are responsible for selecting the most appropriate codes based on the patient's medical record and payer requirements.

HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification.

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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WARNINGS AND PRECAUTIONS

• **Infusion Reactions:** Infusion reactions, including anaphylaxis, can occur. Symptoms can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash, or palpitations. Infusion reactions were observed in 9.3%, 7.4%, and 10.1% of patients treated with UPLIZNA during the randomized controlled periods (RCPs) of Study 1 in patients with NMOSD, Study 2 in patients with IgG4-RD, and Study 3 in patients with gMG, respectively. 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:** Serious, including life-threatening or fatal, bacterial, fungal, and new or reactivated viral infections have been observed during and following completion of treatment with B-cell depleting therapies, including UPLIZNA. The most common infections reported by UPLIZNA-treated patients in the NMOSD randomized and open-label clinical trial periods for NMOSD were urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%), and influenza (7%). In the IgG4-RD RCP, the most common infections reported by UPLIZNA-treated patients were urinary tract infection, influenza, and pneumonia. In the gMG RCP, the most common infections reported by UPLIZNA-treated patients were urinary tract infection and nasopharyngitis. Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

Possible Increased Risk of Immunosuppressant Effects with Other Immunosuppressants: If combining UPLIZNA with another immunosuppressive therapy, consider the potential for increased immunosuppressive effects.

Hepatitis B Virus (HBV) Reactivation: HBV reactivation has been observed with B-cell-depleting therapies, including UPLIZNA. Fulminant hepatitis, hepatic failure, and death caused by HBV reactivation have occurred in patients treated with B-cell depleting therapies. HBV reactivation was observed in a patient treated with UPLIZNA during the gMG clinical trial and in the postmarketing setting. Patients with active or 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 HBV confirmed by positive results for HBsAg and anti-HB tests. For patients who are negative for HBsAg and positive for HBcAb, or who are carriers of HBV (i.e., 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.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

• Infections (cont'd):

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.

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 (at least 10% of patients treated with UPLIZNA and greater than placebo): urinary tract infection and arthralgia in NMOSD; urinary tract infection and lymphopenia in IgG4-RD; headache and infusion-related reactions in gMG.

Please see UPLIZNA [full Prescribing Information](#) at [UPLIZNAhcp.com](#).

Learn more about UPLIZNA and find tools and resources supporting patient access at [UPLIZNAhcp.com](#)

Reference: UPLIZNA (inebilizumab-cdon) prescribing information, Amgen. 2025.