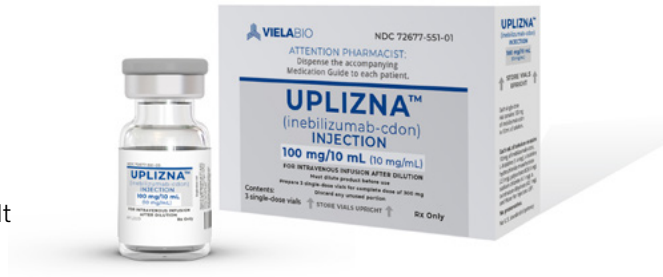
uplizna®
inebilizumab-cdon



Indication
Uplizna® (inebilizumab-cdon) is a CD19-directed cytolytic antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

FDA Approval
Uplizna was approved by the Food and Drug Administration (FDA) on June 11, 2020.

National Drug Code (NDC) for Uplizna	
Code	**Description**
10-digit: 72677-551-01 11-digit: 72677-0551-01	One carton containing three 100 mg/10 mL single-dose vials

Description
Inebilizumab-cdon is a CD19-directed humanized afucosylated IgG1 monoclonal antibody produced by recombinant DNA technology in Chinese hamster ovary (CHO) cell suspension culture. The molecular weight is approximately 149 kDa.

Mechanism of Action
The precise mechanism by which inebilizumab-cdon exerts its therapeutic effects in NMOSD is unknown but is presumed to involve binding to CD19, a cell surface antigen present on pre-B and mature B lymphocytes. Following cell surface binding to B lymphocytes, inebilizumab-cdon results in antibody-dependent cellular cytolysis.

Dosage
Hepatitis B virus, quantitative serum immunoglobulins, and tuberculosis screening are required before the first dose.
Prior to every infusion:
- Determine if there is an active infection
- Premedicate with a corticosteroid, an antihistamine, and an anti-pyretic

Uplizna is administered as an intravenous infusion. The recommended dosage is:
- 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 for chronic usage

How Supplied
Uplizna is a clear to slightly opalescent, colorless to slightly yellow solution supplied as one carton containing three 100 mg/10 mL single-dose vials.

Distribution
Cardinal Health Specialty Distribution
Customer Service: 866-300-3838
Email: Multi-Specialty-Priority@cardinalhealth.com
www.cardinalhealth.com/spd

Metro Medical
Item Number: 755101
Physician Office: 800-768-2002
www.metromedicalorder.com

PANTHERx Specialty Pharmacy, LLC
Phone: 855-726-8479 (412-246-9858)
Fax: 855-246-3986 (412-787-9400)
Email: pharmacist@pantherxrare.com
www.pantherxrare.com

Billing Codes*

ICD-10-CM† Codes for Consideration	
Code	**Description**
G36.0	Neuromyelitis optica (Devic)

HCPCS† Code for Uplizna	
Code	**Description**
J1823	Injection, inebilizumab-cdon, 1mg

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

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

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.

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Please see full Prescribing Information at www.Uplizna.com.