GETTING YOUR PATIENTS STARTED ON UPLIZNA

UPLIZNA®
inebilizumab-cdon

- [ ] Submit a Patient Enrollment Form (PEF) to initiate the process to enroll your patient in Horizon By Your Side, a patient support program*
- [ ] Submit a Prior Authorization (PA) along with any clinical documentation that may be needed

  Common PA criteria include:

  - [ ] Documentation of diagnosis of neuromyelitis optica spectrum disorder (NMOSD) by, or in consultation with, a neurologist
  - [ ] Lab results showing that the patient is positive for anti-aquaporin-4 (AQP4) antibodies; a cell-based assay is preferred
  - [ ] Documentation of clinical signs and symptoms (eg, EDSS score, attack history, and previous treatments along with contraindications and side effects)
  - [ ] Patient must be at least 18 years of age
- [ ] Screenings/vaccinations:
  - [ ] Complete hepatitis B virus, quantitative serum immunoglobulins, and tuberculosis screening before the first dose of UPLIZNA
  - [ ] Administer all immunizations at least 4 weeks prior to initiation of UPLIZNA
- [ ] Identify site of care (SOC) and submit infusion order†

FOR MORE SUPPORT, DOWNLOADABLE RESOURCES ARE AVAILABLE AT UPLIZNAHCP.COM

*A patient signature of consent is required in accordance with HIPAA to complete enrollment in Horizon By Your Side, a patient support program.

†If you do not have a specific preference or need help establishing an SOC, Horizon By Your Side will provide options based on the patient's insurance and location.

EDSS=Expanded Disability Status Scale.

Please see Important Safety Information on next page and Full Prescribing Information at UPLIZNAhcp.com.

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.

Please see Full Prescribing Information at UPLIZNAhcp.com.