Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria UPLIZNA (inebilizumab-cdon)
Original Development Date: Original Effective Date: Revision Date:	August 21, 2020

UPLIZNA™ (inebilizumab-cdon)

LENGTH OF AUTHORIZATION: UP TO ONE YEAR

REVIEW CRITERIA:

- Patient is ≥ 18 years of age; **AND**
- Patient has been diagnosed with neuromyelitis optica spectrum disorder (NMOSD); **AND**
    - Patient must be anti-aquaporin-4 (AQP4) antibody positive; **AND**
    - Patient has a history of ≥ 1 relapses that required rescue therapy within the year prior to screening or 2 ≥ relapses that required rescue therapy in 2 years prior to screening; **AND**
    - Patient has an Expanded Disability Status Score (EDSS) of ≤ 7.5 (e.g., inability to take more than a few steps; restricted to wheelchair and may need aid in transferring; can wheel self but cannot carry on in standard wheelchair for a full day and may require a motorized wheelchair); **AND**
- The prescribing physician must be a neurologist; **AND**
- Submission of negative tuberculin test results prior to initiating therapy; **AND**
- Patient does NOT have an active infection, including clinically important localized infections; **AND**
- Patient is NOT concomitantly receiving therapy with other immunosuppressant drugs; **AND**
- Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment and confirmed negative for active HBV; **AND**
- Patient serum immunoglobulin baseline measured prior to the start of therapy; **AND**
- Patient does NOT have an underlying immunodeficiency disorder (e.g., acquired/congenital primary immunodeficiency, human immunodeficiency virus [HIV]); **AND**
- Patient has NOT received any vaccinations in the 4-weeks prior to the start of therapy

CONTINUATION OF THERAPY:

- Patient met initial review criteria; **AND**
- Clinical response to therapy is submitted; **AND**
- Submission of serum immunoglobulin; **AND**
- Patient is NOT concomitantly receiving therapy with other immunosuppressant drugs; **AND**
- Patient does NOT have an active infection, including clinically important localized infections

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DOSING AND ADMINISTRATION:

- Initial dose: 300 mg intravenous infusion over approximately 90 minutes followed two weeks later by a second 300 mg intravenous infusion
- Subsequent doses (starting 6 months from the first infusion): 300 mg intravenous infusion every 6 months
- Supplied as a 100 mg/10 mL (10 mg/mL) solution in a single-dose vial