Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	August 21, 2020

ENSPRYNG™ (satralizumab-mwge)

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 ≤ 6.5 (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**
- Baseline liver transaminase and neutrophil count is required prior to treatment; **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 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 liver transaminase and neutrophil count; **AND**
- Patient does NOT have an active infection, including clinically important localized infections

DOSING AND ADMINISTRATION:

- Loading dose: 120 mg subcutaneous injection at weeks 0, 2, and 4
- Maintenance doses: 120 mg subcutaneous injection every 4 weeks
- Supplied as a 120 mg/mL single-dose prefilled syringe