

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  $\geq 18$  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  $\geq 1$  relapses that required rescue therapy within the year prior to screening or  $2 \geq$  relapses that required rescue therapy in 2 years prior to screening; **AND**
  - Patient has an Expanded Disability Status Score (EDSS) of  $\leq 6.5$  (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