Satralizumab-mwge (ENSPRYNG) for Neuromyelitis Optica Spectrum Disorder (NMOSD) Criteria for Use December 2024

VA National Formulary Committee and Pharmacy Benefits Management Services

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive satralizumab-mwge.

☐ Untreated active hepatitis B infection
☐ Untreated latent or active tuberculosis infection
☐ Active, clinically significant infection
☐ Active hepatic disease or hepatic impairment
☐ Baseline ALT and/or AST > 1.5 times the upper limit of normal (ULN)
☐ Concomitant therapy with another biologic therapy for neuromyelitis optica spectrum disorder (NMOSD)
☐ Concomitant chronic therapy with intravenous immunoglobulin or plasma exchange (use of these treatments in exacerbations is reasonable)
☐ Pregnancy

Inclusion Criteria

All of the following must be met.

☐ Care provided by VA or VA Community Care neurology provider or locally designated expert
☐ Diagnosis of aquaporin-4 antibody positive NMOSD
☐ Completed hepatitis B screening (HBsAg, total anti-HBc and anti-HBs) and consult referral for hepatitis B management if either HBsAg or total anti-HBc positive ^1
☐ All guideline recommended eligible immunizations administered at least 4 weeks prior to the start of treatment for live or live-attenuated vaccines, and whenever possible, at least 2 weeks prior to the start of treatment for inactivated vaccines
☐ Contraindication, intolerance, or lack of therapeutic response to rituximab OR patient not a candidate for IV rituximab due to inability to access an infusion center or poor venous access

Additional Inclusion Criteria

Select if applicable.

☐ For patients who can become pregnant: Counseling provided on potential risks vs benefits of treatment and to inform their provider of a known or suspected pregnancy

Footnotes

1. HBsAg: Hepatitis B surface antigen; anti-HBs: Hepatitis B surface antibody; anti-HBc: Hepatitis B core antibody

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