Enspryng (satralizumab)

Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

Satralizumab-mwge meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes for the treatment of neuromyelitis optica spectrum disorder (NMOSD) when **ALL** of the following criteria are met:

INITIAL APPROVAL STANDARD REVIEW for up to 12 months:

1. The individual is ≥ 18 years of age (FDA, 2020) **AND**
2. Has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) (FDA, 2020) **AND**
3. Is anti-aquaporin-4 (AQP4) antibody positive (as evidenced by submitted documentation)(FDA, 2020) **AND**
4. History of at least one relapse during the previous 12 months (Yamamura 2019, Traboulsee 2020) **AND**
5. Has an Expanded Disability Status Scale (EDSS) score of 6.5 or less (FDA, 2020) **AND**
6. Will be ordered by or in consultation with a neurologist (FDA, 2020) **AND**
7. Will not be given concomitantly with other biologics or IVIG (FDA, 2020) **AND**
8. Evidence of failure of, contraindication to, or intolerance of rituximab treatment (UpToDate, 2021; Sherman and Han, 2015) **AND**
9. Must be dosed in accordance with the FDA label.

CONTINUED TREATMENT (12 month approval)

1. All the above requirements have been met.
2. There is no evidence or there is a reduction in frequency of relapse of the NMOSD.

Dosage and Administration

Dosing per FDA Guidelines

The recommended loading dosage of Satralizumab-mwge for the first three administrations is 120 mg by subcutaneous injection at weeks 0, 2 and 4, followed by maintenance dosage of 120 mg every 4 weeks.

Prior to first dose of Satralizumab-mwge, must have the following screening: Hepatitis B virus, tuberculosis screening, and liver transaminase screening.

Satralizumab-mwge is available in a single-dose prefilled syringe.

Please refer to a separate policy on Site of Care or Site of Service Review (policy #2018030) for pharmacologic/biologic medications.

Does Not Meet Primary Coverage Criteria Or Is Investigational For Contracts Without Primary Coverage Criteria

Satralizumab-mwge does not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes for all other indications.

For members with contracts without primary coverage criteria, the use of Satralizumab-mwge for the use of any other indication is considered **investigationa**l. **Investigational** services are specific contract exclusions in most member benefit certificates of coverage.