Clinical Policy: Satralizumab-mwge (Enspryng)

Reference Number: ERX.SPA.365
Effective Date: 08.14.20
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Satralizumab-mwge (Enspryng™) is an anti-interleukin-6 receptor antagonist.

FDA Approved Indication(s)
Enspryng is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Enspryng is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Neuromyelitis Optica Spectrum Disorder (must meet all)**:**

1. Diagnosis of NMOSD;
2. Prescribed by or in in consultation with a neurologist;
3. Age ≥ 18 years;
4. Member has positive serologic test for anti-AQP4 antibodies;
5. Member has experienced at least one relapse within the previous 12 months;
6. Member has a history of at least two relapses during the previous 24 months;
7. Baseline expanded disability status scale (EDSS) score of ≤ 6.5;
8. Failure of rituximab (*Ruxience™ is preferred*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for rituximab*
9. At the time of request, member does not have active hepatitis B infection (positive results for hepatitis B surface antigen and anti-hepatitis B virus tests) or active or untreated latent tuberculosis;
10. Enspryng is not prescribed concurrently with rituximab, Soliris®, or Uplizna®;
11. Dose does not exceed 120 mg at weeks 0, 2, and 4, and every 4 weeks thereafter.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Neuromyelitis Optica Spectrum Disorder (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy – including but not limited to improvement or stabilization in any of the following parameters:
   a. Frequency of relapse;

b. EDSS;
c. Visual acuity;
3. Enspryng is not prescribed concurrently with rituximab, Soliris, or Uplizna;
4. If request is for a dose increase, new dose does not exceed 120 mg every 4 weeks.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AQP-4: aquaporin-4
EDSS: expanded disability status scale
FDA: Food and Drug Administration
NMOSD: neuromyelitis optica spectrum disorder

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Rituxan®/Riabni™/Ruxience™/ Truxima® (rituximab)*	375 mg/m^2 per week for 4 weeks as induction, followed by 375 mg/m^2 biweekly every 6 to 12 months	See regimen

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to satralizumab or any of the inactive ingredients, active hepatitis B infection, active or untreated latent tuberculosis
- Boxed warning(s): none reported

Appendix D: General Information

- AQP-4-IgG-seropositive status is confirmed with the use of commercially available cell-binding kit assay (Euroimmun).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NMOSD	120 mg SC at weeks 0, 2, 4, and every 4 weeks thereafter	See regimen

VI. Product Availability

Solution for injection in a single-dose prefilled syringe: 120 mg/mL

VII. References

1. Enspryng Prescribing Information. South San Francisco, CA: Genentech, Inc.; August 2020. Available at: https://www.enspryng.com. Accessed September 15, 2021.
2. Yamamura T, Kleiter I, Fujihara K, et al. Trial of satralizumab in neuromyelitis optica spectrum disorder. N Engl J Med. 2019; 381: 2114-2124.

3. Traboulsee A, Greenberg BM, Bennett JL, et al. Safety and efficacy of satralizumab monotherapy in neuromyelitis optica spectrum disorder: a randomised, double-blind, multicentre, placebo-controlled phase 3 trial. Lancet Neurol. 2020; 19(5): 402-412.
4. Sellner J, Boggild M, Clanet M, et al. EFNS guidelines on diagnosis and management of neuromyelitis optica. European Journal of Neurology. 2010; 17: 1019–1032.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.21.20	02.20
1Q 2021 annual review: drug is now FDA approved - criteria updated per FDA labeling: added requirement that member does not have active HBV or TB since both are contraindications; added requirement for trial of rituximab; added requirement against concurrent use with rituximab, Soliris, or Uplizna; references reviewed and updated.	09.29.20	02.21
1Q 2022 annual review: no significant changes; specified that Ruxience is the preferred rituximab product; references reviewed and updated.	09.15.21	02.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.