Clinical Policy: Satralizumab-mwge (Enspryng)

Reference Number: LA.PHAR.463
Effective Date:
Last Review Date: 03.21 Coding Implications
Line of Business: 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

Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections 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 the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

II. Continued Therapy

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

1. **Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met all 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 (must meet 1 or 2):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.**
   Approval duration: Duration of request or 6 months (whichever is less); or
2. **Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

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 –LA.PMN.53 for Medicaid 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 require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Rituxan®/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.accessdata.fda.gov/drugsatfda_docs/label/2020/761149s000lbl.pdf. Accessed August 24, 2020.**
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.**

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
TBD	Injection, satralizumab-mwge, 120 mg

Reviews, Revisions, and Approvals	Date
Converted corporate to local policy	03.2021

Reviews, Revisions, and Approvals	Date

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. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.