JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS131
		Effective Date	01/20/2021
		Review Date	01/20/2021
	Subject **Enspryng**	*Revision Date*	12/08/2021
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Enspryng, satralizumab-mwge

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I. POLICY

Enspryng (satralizumab-mwge) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Enspryng** may be approved for patients meeting the following:
   1. Patient is 18 years of age or older
   2. Documented diagnosis of neuromyelitis optica spectrum disorder (NMOSD)
   3. Documentation showing the following:
      1. NMOSD is seropositive with laboratory confirmation evidenced by the presence of anti- aquaporin-4 (AQP4) antibodies
      2. Patient has had at least one neuromyelitis optica relapse in the previous 12 months
   4. Prescriber is, or has consulted with, an ophthalmologist or neurologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial therapy may be approved for 12 months

B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient has had a beneficial response, evidenced by a reduction in relapse frequency

IV. EXCLUSIONS

A. Enspryng will not be approved for the following:
   1. Concomitant use with other monoclonal antibody and immunosuppressant therapies (Soliris [eculizumab], Uplizna [inebilizumab], rituximab therapy, etc.)

2. Concomitant use with disease modifying therapies for the treatment of multiple sclerosis (e.g. Tecfidera [dimethyl fumarate], Gilenya [fingolimod], Copaxone [glatiramer acetate], Ocrevus [ocrelizumab], etc.)
3. Patients that are anti-AQP4 antibody negative
4. Patients with active hepatitis B (HBV) infection
5. Patients with active, or untreated latent tuberculosis
6. Any indications or uses that are not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Enspryng [prescribing information]. South San Francisco, CA: Genentech, Inc.; August 2020
2. Yamamura T, Kleiter I, Fujihara K, et al. Trial of satralizumab in neuromyelitis optica spectrum disorder. N Engl J Med. 2019;381(22):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.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
01/20/2021	Policy Creation
12/08/2021	Updated Exclusions section regarding physician samples

Review Date: 01/20/2021

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