

STATE OF WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Services Prior Authorization Criteria Enspryng[®] (Satralizumab) Effective 3/1/2021

Prior Authorization Request Form

Enspryng (Satralizumab) is an antagonist of the interleukin-6 (IL-6) receptor. Satralizumab is presumed to inhibit IL-6-mediated signaling through binding to soluble and membrane-bound IL-6 receptors. It is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

CRITERIA FOR APROVAL:

- Patient must have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) confirmed by an anti-aquaporin-4 (AQP4) antibody positive blood serum test; AND
- 2. Patient must have one of the core clinical characteristics from the following:
 - a. Optic neuritis,
 - b. Acute myelitis,
 - c. Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting,
 - d. Acute brainstem syndrome,
 - e. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, or
 - f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions; AND
- 3. Patient must be 18 years of age or older; AND
- 4. Enspryng must be prescribed by, or in consultation with, a neurologist; AND
- 5. Patient has a history of \geq 1 relapses that required rescue therapy within the past 12 months or 2 \geq relapses that required rescue therapy in the past two years, at least one of which must have occurred in the previous year; **AND**
- 6. Patient has an Expanded Disability Status Score (EDSS) of \leq 6.5; **AND**
- The patient is currently receiving or has had a previous 8-week trial with, contraindication to, or intolerance to at least <u>ONE</u> of the following systemic therapies: Azathioprine, Corticosteroids, Mycophenolate mofetil or Rituximab.



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- 8. Patient must NOT have an active hepatitis B infection; AND
- 9. Patient must NOT have active or untreated latent tuberculosis; AND
- 10. Enspryng will not be concurrently used with Soliris, Uplizna or Rituximab.

Initial approval will be for 6 months.

Continuation of therapy:

May be granted if documentation is provided showing patient achieves or maintains a positive clinical response with Enspryng demonstrated by reduction in relapse rate, reduction in symptoms (such as pain, fatigue, motor function), or a slowing progression in symptoms.

Continuation approval will be for 12 months.

References:

- 1.) Enspryng Package Insert
- 2.) Lexi-Comp Clinical Application 2/2021
- 3.) UpToDate Clinical monograph: Neuromyelitis optica spectrum disorders reviewed 2/2021
- 4.) Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N Engl J Med 2019; 381:2114.