CVS Caremark®

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| Reference number(s) |
| 4100-A |

# Specialty Guideline Management Enspryng

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Enspryng | satralizumab-mwge |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-approved Indications1

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

All other indications are considered experimental/investigational and not medically necessary.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:

* For initial requests: Immunoassay used to confirm anti-aquaporin-4 (AQP4) antibody is present.
* For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

## Coverage Criteria

### Neuromyelitis optica spectrum disorder (NMOSD)1,2

Authorization of 12 months may be granted for treatment of neuromyelitis optica spectrum disorder (NMOSD) when all of the following criteria are met:

* Anti-aquaporin-4 (AQPR) antibody positive.
* Member exhibits one of the following core clinical characteristics of NMOSD:
  + Optic neuritis
  + Acute myelitis
  + Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting)
  + Acute brainstem syndrome
  + Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic magnetic resonance imaging (MRI) lesions
  + Symptomatic cerebral syndrome with NMOSD-typical brain lesions
* The member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD.

## Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when all of the following criteria are met:

* The member demonstrates a positive response to therapy (e.g., reduction in number of relapses).
* The member will not receive the requested drug concomitantly with other biologics for the treatment of NMOSD.

## References

1. Enspryng [package insert]. South San Francisco, CA: Genentech, Inc.; March 2022.
2. Wingerchuk DM, Banwell B, Bennett JL, et al. International consensus diagnostic criteria for neuromyelitis optica spectrum disorders. Neurology. 2015; 85:177-189.