SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process may be delayed.**

Drug Requested: Enspryng™ (satralizumab-mwge) **(Pharmacy)**
Neuromyelitis Optica Spectrum Disorder (NMOSD)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Recommended dosage: Loading dose: 120 mg once every 2 weeks for 3 doses (weeks 0, 2, and 4), followed by maintenance dose: 120 mg once every 4 weeks. Maximum quantity: 120mg every 4 weeks.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization Approval: 6 months

- ❑ Prescribing physician must be a neurologist

AND

- ❑ Member must be 18 years of age or older

AND

- ❑ Must submit medical records (e.g., chart notes, laboratory values, etc.) to support a diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD) confirming all of the following:

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- ❑ Past medical history of one of the following:
  - ❑ 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 MRI lesions
  - ❑ Symptomatic cerebral syndrome with NMOSD-typical brain lesions

AND

- ❑ Positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMP-IgG antibodies **(must submit lab results)**

AND

- ❑ Diagnosis of multiple sclerosis or other diagnoses have been ruled out

AND

- ❑ Member has a history of at least one relapse during the previous 12 months prior to initiating Enspryng™ or member has a history of at least two relapses during the previous 24 months, at least one relapse occurring within the past 12 months prior to initiating Enspryng™

  {A historical relapse is defined as a new onset of neurologic symptoms or worsening of existing neurologic symptoms with an objective change on neurologic examination (clinical findings, magnetic resonance imaging findings, or both) that persist for more than 24 hours and/or the new onset of neurologic symptoms or worsening of existing neurologic symptoms that require treatment.}

AND

- ❑ Member must have documentation of an inadequate response or intolerance with rituximab during the 12 months prior to initiating Enspryng™

OR

- ❑ If member has a documented contraindication to rituximab, member must have failed the following treatment during the 12 months prior to initiating Enspryng™
  - ❑ Member must have failed at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate, etc.)

OR

  - ❑ Member must have failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG)

AND

- ❑ Member does not have an active infection, including clinically important localized infections

AND

- ❑ Provider has submitted a baseline liver transaminase and neutrophil count prior to treatment and will continue to monitor throughout treatment

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AND

- ❑ Member has been evaluated and screened for the presence of latent TB infection prior to initiating treatment

AND

- ❑ Member has been evaluated and screened for the presence hepatitis B virus (HBV) prior to initiating treatment

AND

- ❑ Enspryng™ will not be used in combination with disease-modifying therapies for the treatment of multiple sclerosis (e.g., Gilenya (fingolimod), Tecfidera (dimethyl fumarate), Ocrevus (ocrelizumab), etc.)

AND

- ❑ Enspryng™ will not be used in combination with other complement inhibitor therapy (e.g., eculizumab), IL6-inhibitors (e.g., toclizumab), anti-CD20-directed antibody therapy (e.g., rituximab) or anti-CD19 directed antibody therapy (ineblizumab-cdon)

Reauthorization Approval: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet the initial criteria

AND

- ❑ Absence of unacceptable toxicity from therapy (i.e., tuberculosis (TB) infections, hepatitis B reactivation, infusion reactions, serious infections)

AND

- ❑ Provider must submit clinical notes documenting clinical improvement (fewer relapses from baseline) or stabilization of patient relapses while on Enspryng™ therapy

Note: Add on, dose escalation of immunosuppressive therapy, or additional rescue therapy from baseline to treat NMOSD or exacerbation of symptoms while on therapy will be considered as treatment failure.

Medication being provided by Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****