SENTARA HEALTH PLANS

MEDICAL 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 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Uplizna™ (inebilizumab-cdon) **IV (J3590) NDC 72677-0551-01 (Medical)**
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: Maximum Units (per dose and over time)

- 300 billable units on day 1 and 15, then 300 billable units every 6 months (beginning 6 months after the first dose)

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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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**:
  - ❑ 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 Uplizna™ 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 Uplizna™

  {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, contraindication or intolerance with **BOTH** rituximab **AND** Enspryng™ (requires prior authorization) during the 12 months prior to initiating Uplizna™

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AND

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

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

- ❑ Provider attests to monitoring serum immunoglobulin levels during treatment; discontinuation of Uplizna™ should be considered if the patient has low IgG or IgM levels, develops a serious opportunistic infection or prolonged hypogammaglobinemia requiring treatment with IVIG

AND

- ❑ Uplizna™ 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

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

❑ **Reauthorization Approval: 6 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, Progressive Multifocal Leukoencephalopathy (PML), hypogammaglobulinemia, etc.)

AND

- ❑ Provider must submit clinical notes documenting clinical improvement (fewer relapses from baseline) or stabilization of patient relapses while on Uplizna™ 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. Uplizna™ therapy has not been studied with other immunosuppressants.

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Medication being provided by (check box below that applies):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****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.****

***Approved by Pharmacy and Therapeutics Committee**: 11/19/2020
REVISED/UPDATED: ~~4/1/2021;~~ **6/14/2021**;