

**SOUTH DAKOTA MEDICAID
PRIOR AUTHORIZATION CRITERIA**

Physician Administered Drugs, Vaccines, and Immunizations

Inebilizumab (Uplizna) – PA Criteria

HCPC: J1823

Uplizna is an anti-CD19 monoclonal antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) and Immunoglobulin G4-related disease in adults. It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

- **Initial Therapy (must meet all):**
 - Individual is ≥18 years of age
 - Therapy meets the following criteria as specified per indication:
 - For NMOSD (must meet all):
 - Therapy is prescribed by or in consultation with a neurologist
 - Individual has a documented diagnosis of NMOSD with presence of seropositive aquaporin-4 (AQP4) antibodies
 - Individual has symptoms consistent with **at least one** core clinical characteristic as below:
 - Optic neuritis
 - Acute myelitis
 - Area postrema syndrome or episode of otherwise unexplained hiccups or nausea and vomiting
 - Acute brainstem syndrome
 - Symptomatic narcolepsy
 - Acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
 - Symptomatic cerebral syndrome with NMOSD-typical brain lesions
 - Documentation is provided indicating previous failure, contraindication or intolerance to **one** of the following:
 - Rituximab
 - Tocilizumab
 - Documentation is provided indicating at least one relapse in the last 12 months or two relapses in the last 2 years
 - Therapy is not being used in combination with other biologics for NMOSD (eculizumab, rituximab, satralizumab, tocilizumab, etc.)
 - Individual has an Expanded Disability Status Score (EDSS) score documented at baseline
 - Approval duration: 12 months
 - For Immunoglobulin G4-related disease (must meet all):
 - Therapy is prescribed by or in consultation with a rheumatologist, gastroenterologist, nephrologist, or pulmonologist
 - Individual has a diagnosis of immunoglobulin G4-related disease
 - Individual meets **one** of the following:
 - Documentation is submitted indicating at least 1 organ system involvement in addition to failure, contraindication, and/or current use of steroids with progression of symptoms
 - Documentation is submitted indicating multisystem (≥2) organ involvement and concurrent initiation of steroid therapy
 - Documentation is provided indicating previous failure, contraindication or intolerance to rituximab
 - Approval duration: 12 months

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- **Continuation of Therapy (must meet all):**
 - Therapy is not prescribed in combination with other biologics for the requested indication
 - Therapy meets the following criteria as specified per indication
 - For NMOSD (must meet all):
 - Individual has had a positive clinical response with reduction in number and/or severity of relapses or signs and symptoms of NMOSD
 - Documentation is provided indicating recent (within 2 months) EDSS
 - Approval duration: 1 year
 - For Immunoglobulin G4-related disease (must meet all):
 - Individual has had a positive response to therapy as indicated by improvement in symptoms, disease flares and/or need for corticosteroids
 - Approval duration: 1 year