Physician Administered Drugs, Vaccines, and Immunizations

## Inebilizumab (Uplizna) - PA Criteria

HCPC: J1823

Uplizna is an anti-CD19 monoclonal antibody for the treatment of adults with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive. It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

## • Initial Therapy (must meet all):

- Therapy is prescribed by or in consultation with a neurologist
- o Individual is ≥18 years of age
- o Documentation is submitted indicating presence of seropositive aquaporin-4 (AQP4) antibodies
- o Individual has a documented diagnosis of NMOSD 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 is provided
- 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
- o Approval duration: 12 months

## • Continuation of Therapy (must meet all):

- o Initial criteria has been met
- Documentation of positive clinical response with reduction in the number and/or severity of relapses or signs and symptoms of NMOSD
- o Documentation is provided indicating recent (within 2 months) EDSS
- o Approval duration: 12 months

