Inebilizumab (Uplizna) – PA Criteria

HCPC: J1823

Uplizna is an anti-CD19 monoclonal antibody indicated for the treatment of adults with neuromyelitis optica spectrum disorder (NMOSD), Immunoglobulin G4-related disease and anti-acetylcholine receptor antibody-positive (AChR+) or antimuscle-specific tyrosine kinase (MuSK) antibody-positive generalized myasthenia gravis (gMG). 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
- For gMG (must meet all):
  - Therapy is requested by or in consultation with a neurologist
  - Individual has a documented diagnosis of gMG with labs confirming the presence of **one** of the following:
    - Anti-AChR antibodies
    - Anti-MuSK antibodies
  - Individual has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II-IV disease
  - Documentation is submitted indicating the patient's baseline Quantitative Myasthenia Gravis (QMG) score
  - MG-Activities of Daily Living (MG-ADL) total score of ≥6
  - Individual meets previous therapy trials as specified per indication
    - AChR+ Disease (must meet all):
      - Documentation is provided indicating inadequate response or contraindication to pyridostigmine and corticosteroids
      - Individual has failed treatment with at least 2 immunosuppressive therapies (ex., azathioprine, cyclosporine, mycophenolate, cyclophosphamide, methotrexate, tacrolimus etc.) over the course of the last 12 months OR has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis, plasma exchange (PE) or intravenous immunoglobulin (IVIG)
    - MuSK+ Disease (must meet all):
      - Documentation is provided indicating inadequate response or contraindication to corticosteroids
      - Documentation is provided indicating failure, contraindication or inadequate response to rituximab
  - Therapy is not prescribed in combination with other biologics for gMG (e.g. Ultomiris, Zilbrysq, Rystiggo, Vyvgart, Vyvgart Hytrulo, etc.)
  - Approval duration: 9 months

- **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 the number and/or severity of relapses or signs and symptoms of NMOSD
      - Documentation is provided indicating recent (within 2 months) EDSS
      - Approval duration: 12 months
    - 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
    - For gMG renewal (must meet all):
      - Improvement (reduction in score) in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score from pretreatment baseline
      - Improvement in the Quantitative Myasthenia Gravis (QMG) total score
      - Approval duration: 1 year