Nipocalimab (Imaavy) – PA Criteria

HCPC: J9256

Nipocalimab (Imaavy) is a neonatal Fc receptor antagonist, monoclonal antibody indicated for the treatment of generalized myasthenia gravis in adult and pediatric patients ≥12 years of age who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) 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 requested by or in consultation with a neurologist
  - Individual is ≥ 12 years of age
  - 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)
      - Documentation is provided indicating previous failure, contraindication or intolerance to inebilizumab (Uplizna)
    - 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
      - Documentation is provided indicating previous failure, contraindication or intolerance to inebilizumab (Uplizna)
  - Therapy is not prescribed in combination with other biologics for gMG (e.g. Ultomiris, Zilbrysq, Rystiggo, Vyvgart, Vyvgart Hytrulo, etc.)
  - Approval duration: 6 months
- **Continuation of Therapy (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