Efgartigimod alfa (Vyvgart) – PA Criteria

HCPC: J9332

Efgartigimod alfa (Vyvgart) is a human igG1 antibody fragment that binds to the neonatal Fc receptor resulting in a reduction of circulating IgG. It is indicated for the treatment of myasthenia gravis in adults who are anti-acetylcholine receptor antibody positive (AChR+) and 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
  - Individual is ≥18 years of age
  - Individual has a documented diagnosis of gMG with labs confirming presence of anti-ACHR 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 ≥5
  - 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)
  - Therapy will not be used in combination with other biologic therapies (Ex. Rituximab, Ultomiris, Soliris)
  - 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