

**Efgartigimod alfa and hyaluronidase (Vyvgart Hytrulo) – PA Criteria**

HCPC: J9334

Efgartigimod alfa and hyaluronidase (Vyvgart Hytrulo) is a combination of efgartigimod alfa, a neonatal Fc receptor blocker, and hyaluronidase, an endoglycosidase. It is indicated for treatment in adults with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor antibody positive (AChR+) and for chronic inflammatory demyelinating polyneuropathy (CIDP). 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 gMG (must meet all):
    - Therapy is prescribed by or in consultation with a neurologist
    - 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)
    - Individual has failed therapy with efgartigimod alfa (Vyvgart)
    - Therapy is not prescribed in combination with other biologics for gMG (Ex. Rituximab, Ultomiris, Soliris, etc.)
    - Approval duration: 6 months
  - For CIDP
    - Therapy is prescribed by or in consultation with a neurologist or neuromuscular specialist
    - Individual has a documented diagnosis of CIDP that has been confirmed via electrodiagnostic testing
    - Baseline level of functional status is documented (E.g. ambulatory status with/without assist devices, ability to perform ADLs, etc.)
    - Documentation is provided indicating failure, contraindication or intolerance to **all** the following:
      - IVIG
      - Plasma Exchange
      - Steroids
      - Rituximab
    - Therapy will not be used in conjunction with IVIG therapy, a complement inhibitor (e.g. Soliris, Ultomiris) or another FcRN antagonist (e.g. Rystiggo)
    - Approval duration: 3 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 gMG (must meet all):

**SOUTH DAKOTA MEDICAID  
PRIOR AUTHORIZATION CRITERIA**

*Physician Administered Drugs, Vaccines, and Immunizations*

- 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
- For CIDP (must meet all):
  - Documentation is provided indicating positive response to therapy
  - Approval duration: 1 year