

## SPECIALTY GUIDELINE MANAGEMENT

### VYVGART (efgartigimod alfa-fcab) VYVGART HYTRULO (efgartigimod alfa and hyaluronidase-qvfc)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

###### FDA-Approved Indication

Vyvgart is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Vyvgart Hytrulo is indicated for the treatment of:

- A. Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.
- B. Adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

All other indications are considered experimental/investigational and not medically necessary.

##### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. For initial requests, chart notes, medical records, or claims history documenting:
  1. Generalized myasthenia gravis:
    - i. Positive anti-acetylcholine receptor (AChR) antibody test
    - ii. Myasthenia Gravis Foundation of America (MGFA) clinical classification
    - iii. MG activities of daily living score
    - iv. Previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reasons to avoid therapy.
  2. Chronic inflammatory demyelinating polyneuropathy:
    - i. Electrodiagnostic testing (e.g., electromyography (EMG), nerve conduction studies (NCS))
    - ii. Previous therapies tried (e.g., immunoglobulins, corticosteroids, or plasma exchange), including response to therapy. If therapy is not advisable, documentation of clinical reasons to avoid therapy.
- B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

##### III. CRITERIA FOR INITIAL APPROVAL

**A. Generalized myasthenia gravis (gMG)**

Authorization of 6 months may be granted for treatment of generalized myasthenia gravis (gMG) when all of the following criteria are met:

1. Anti-acetylcholine receptor (AChR) antibody positive
2. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
3. MG activities of daily living (MG-ADL) total score of greater than or equal to 5
4. Meets one of the following:
  - i. Member has had an inadequate response or intolerable adverse event to at least two immunosuppressive therapies over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, tacrolimus)
  - ii. Member has had an inadequate response or intolerable adverse event to at least one immunosuppressive therapy and intravenous immunoglobulin (IVIG) over the course of at least 12 months
  - iii. Member has a documented clinical reason to avoid therapy with immunosuppressive agents and IVIG
5. The requested medication will not be used in combination with another neonatal Fc receptor blocker (e.g., Rystiggo) or complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq)

**B. Chronic inflammatory demyelinating polyneuropathy (CIDP) (Vyvgart Hytrulo Only)**

Authorization of 6 months may be granted for treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) when all of the following criteria are met:

1. Disease course is progressive or relapsing/remitting for 2 months or longer
2. Diagnosis was confirmed by electrodiagnostic testing (consistent with EFNS/PNS guidelines)
3. Meets one of the following:
  - i. Member has had an inadequate response or intolerable adverse event to immunoglobulins, corticosteroids, or plasma exchange
  - ii. Member has a documented clinical reason to avoid therapy with immunoglobulins, corticosteroids, or plasma exchange

**IV. CONTINUATION OF THERAPY**

**A. Generalized myasthenia gravis (gMG)**

Authorization of 12 months may be granted for continued treatment of generalized myasthenia gravis (gMG) in members requesting reauthorization when all of the following criteria are met:

1. There is no evidence of unacceptable toxicity or disease progression while on the current regimen
2. Member demonstrates a positive response to therapy (e.g., improvement in MG-ADL score, MG Manual Muscle Test (MMT), MG Composite)
3. The requested medication will not be used in combination with another neonatal Fc receptor blocker (e.g., Rystiggo) or complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq)

**B. Chronic inflammatory demyelinating polyneuropathy (CIDP) (Vyvgart Hytrulo Only)**

Authorization of 12 months may be granted for treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) when all of the following criteria are met:

1. There is no evidence of unacceptable toxicity or disease progression while on the current regimen
2. Member demonstrates a positive response to therapy (e.g., improvement in Inflammatory Rasch-built Overall Disability Scale (I-RODS), Inflammatory Neuropathy Cause and Treatment (INCAT) disability scale, Medical Research Council (MRC) Sum score, grip strength)

## V. REFERENCES

1. Vyvgart [package insert]. Boston, MA: Argenx US, Inc.; January 2024.
2. Vyvgart Hytrulo [package insert]. Boston, MA: Argenx US, Inc.; June 2024.
3. Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2021; 96 (3) 114-122.
4. Howard JF, Bril V, Vu T, et al. Safety, efficacy, and tolerability of efgartigimod in patients with generalised myasthenia gravis (ADAPT): a multicentre, randomised, placebo-controlled, phase 3 trial. *Lancet Neurol*. 2021. 20:526-536.
5. Barnett C, Herbelin L, Dimachkie MM, Barohn RJ. Measuring Clinical Treatment Response in Myasthenia Gravis. *Neurol Clin*. 2018 May;36(2):339-353.
6. Van den Bergh PY, Hadden RD, van Doorn PA, et al. European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of chronic inflammatory demyelinating polyradiculoneuropathy: report of a joint task force of the European Federation of Neurological Societies and the Peripheral Nerve Society - second revision. *Eur J Neurol*. 2021;28(11):3556-3583.