

Reference number(s)
5102-A

# SPECIALTY GUIDELINE MANAGEMENT

## VYVGART (efgartigimod alfa-fcab)

### 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.

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. Positive anti-acetylcholine receptor (AChR) antibody test
  - 2. Clinical classification of myasthenia gravis score
  - 3. MG activities of daily living score
  - 4. Use of an acetylcholinesterase (AChE) inhibitor, steroid, or non-steroidal immunosuppressive therapy (NSIST)
- B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

#### III. CRITERIA FOR INITIAL APPROVAL

##### **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 5 or more with at least 50% of the score due to non-ocular symptoms
- 4. On a stable dose of at least one of the following:
  - a. Acetylcholinesterase inhibitors (e.g., pyridostigmine)
  - b. Steroids (at least 3 months of treatment)
  - c. Nonsteroidal immunosuppressive therapy (NSIST) (at least 6 months of treatment) (e.g., azathioprine, mycophenolate mofetil)

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#### IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and member demonstrates a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score).

#### V. REFERENCES

1. Vyvgart [package insert]. Boston, MA: Argenx US, Inc.; December 2021.
2. Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2021; 96 (3) 114-122.
3. 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.