Vyvgart (efgartigimod alfa-fcab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Vyvgart (efgartigimod alfa-fcab) drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits 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.

POLICY

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.

Criteria for Initial Approval

© 2022 CVS Caremark®. All rights reserved.

A. Vyvgart (efgartigimod alfa-fcab) may be considered **medically necessary** for the treatment of generalized myasthenia gravis (gMG) when all of the following criteria are met:
    1. Member is anti-acetylcholine receptor (AChR) antibody positive
    2. Member has Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
    3. Member has a 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. Member is 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)

Approval is for **6 months.**

Continuation of Therapy

A. Vyvgart (efgartigimod alfa-fcab) may be considered **medically necessary** for the continued treatment of generalized myasthenia gravis (gMG) 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).

Approval is for **6 months.**

Vyvgart (efgartigimod alfa-fcab) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Medication	FDA-recommended dosing
Vyvgart (efgartiigimod alfa-fcab) 400 mg/20 mL single-dose vial	• The recommended dosage is 10 mg/kg administered as an intravenous infusion over one hour once weekly for 4 weeks. In patients weighing 120 kg or more, the recommended dose is 1200 mg per infusion. • Administer subsequent treatment cycles based on clinical evaluation; the safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9332 Injection, efgartigimod 2mg

REFERENCES

- Vyvgart [package insert]. Boston, MA: Argenx US, Inc.; December 2021.

© 2022 CVS Caremark®. All rights reserved.

- Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2021; 96 (3) 114-122.
- 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.

*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.04.56
Original Effective Date: May 20, 2022
Reviewed: July 2022
Revised:
Current Effective Date: May 20, 2022

© 2022 CVS Caremark®. All rights reserved.