RX.PA.078.CCH VYVGART (EFGARTIGIMOD ALFA-FCAB)

The purpose of this policy is to define the prior authorization process for Vyvgart (efgartigimod alfa-fcab) for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

DEFINITIONS

gMG = generalized Myasthenia Gravis

M**yasthenia Gravis Foundation of America (MGFA) Disease Clinical Classification**

Class I	Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal.
Class II	Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity. • IIa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles. • IIb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
Class III	Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity. • IIIa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles. • IIIb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
Class IV	Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity. • IVa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles. • IVb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both
Class V	Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management. The use of a feeding tube without intubation places the patient in class IVb.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Vyvgart (efgartigimod alfa-fcab), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed under the respective diagnosis:

- Must be age 18 years or older
- Must be prescribed by, or in consultation with, a neurologist
- Must have a diagnosis of myasthenia gravis, Foundation of America class II, III, or IV
- Must have documentation of a positive serologic test for anti-acetylcholine receptor (AChR) antibody
- Must have a trial and failure, contraindication, or intolerance to at least ONE corticosteroid (e.g., prednisone)
- Must have a trial and failure or contraindication to at least ONE of the following (or intolerance of all):
    - At least TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate)
    - At least ONE non-steroidal immunosuppressive therapy while on chronic plasmapheresis or plasma exchange
- Must have documentation of a baseline score using a validated gMG instrument [e.g., the MG-QOL 15 tool, the Myasthenia Gravis Activities of Daily Living (MG-ADL) tool]
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon the following:

- Must have documentation of improvement from the member's baseline score using a validated gMG instrument [e.g., the MG-QOL 15 tool, the Myasthenia Gravis Activities of Daily Living (MG-ADL) tool]
    - For subsequent reauthorizations, stability in the score may be accepted after initial improvement
- Planned administration of next dose must be ≥ 50 days since the START of the previous cycle of Vyvgart
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 2 months
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J9332	Vyvgart	Injection, efgartigimod alfa-fcab, 2mg

REFERENCES

1. Vyvgart [Prescribing Information]. Zwijnaarde, Belgium: Argenx BV; April 2022.

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	XX/XX

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

Disclaimer

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CountyCare reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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