



**IgG-1 Monoclonal Antibody
Vyvgart (Efgartimod Alfa-fcab) J9332
Prior Authorization Request
Medicare Part B Form**

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

Date Requested _____

Requestor _____ Clinic name: _____ Phone _____ / Fax _____

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCCP Code	Name of Drug <input type="checkbox"/> Self-administered	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Chart notes attached. **Other important information:** _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)
 Provider has reviewed the attached “Criteria for Approval” and attests the member meets ALL required PA criteria.
 If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)
 Provider has reviewed the attached “Criteria for Continuation” and attests the member meets ALL required PA Continuation criteria.
 Patient had an adequate response or significant improvement while on this medication.
 If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.
THIS AUTHORIZATION DOES NOT GUARANTEE PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – IgG-1 Monoclonal Antibody PA

Drug Name(s):

VYVGART

EFGARTIGIMOD ALFA-FCAB

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. **Drug meets the following utilization management criteria:**
 - a. Documented trial and failure to 2 immunosuppressants
 - i. Failure is defined as an inability to improve the condition after at least 1 year of treatment
 - ii. Immunosuppressants include azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus
 - b. Baseline Myasthenia-Gravis Activities of Daily Living (MG-ADL) of at least 5
3. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

- N/A

Prescriber Restrictions:

- Must be prescribed by, or in consultation with, a neurologist

Coverage Duration:

Approval will be for 6 months

- Must have a documented response to therapy evidenced by at least a 2-point reduction in the MG-ADL total score from baseline for reauthorization

FDA Indications:

- Myasthenia gravis, Anti-acetylcholine antibody positive

Off-Label Uses:

Vyvgart

- N/A

Age Restrictions:

- Safety and effectiveness have not been established in pediatric patients

Other Clinical Consideration:

- N/A

Resources:

https://www-micromedexsolutions-com.liboff.ohsu.edu/micromedex2/librarian/CS/A5E163/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/955E51/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=933502&contentSetId=100&title=Efgartigimod+Alfa-fcab&servicesTitle=Efgartigimod+Alfa-fcab&brandName=Vyvgart&UserMdxSearchTerm=vyvgart&=null#