



**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.

<input type="checkbox"/>	<b>Standard Request– (72 Hours)</b>	<input type="checkbox"/>	<b>Urgent Request</b> (standard time frame could place the member's life, health or ability in serious jeopardy)
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**

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____ )	Frequency	End Date if known

Self-administered       Provider-administered       Home Infusion

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)**

- Documented trial and failure to 2 immunosuppressants
  - Failure is defined as an inability to improve the condition after at least 1 year of treatment
  - Immunosuppressants include azathioprine, cyclosporine, methotrexate, mycophenolate, tacrolimus
- Baseline Myasthenia-Gravis Activities of Daily Living (MG-ADL) of at least 5

If not, please provide **clinical rationale** for formulary exception: \_\_\_\_\_

**Continuation Requests: (Clinical documentation required for all requests)**

- 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

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 IS NOT A GUARANTEE OF 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 Drug 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. 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**

### FDA Indications:

**Vyvgart**

- Myasthenia gravis, Anti-acetylcholine antibody positive

### Age Restrictions:

Safety and effectiveness have not been established in pediatric patients

### Other Clinical Consideration:

**N/A**

### Resources:

[https://www-micromedexolutions-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](https://www-micromedexolutions-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)