ATRIO HEALTH PLANS

Myasthenia Gravis
Vyvgart (efgartimod alfa-fcab) J9332
Rystiggo (rozanolixizumab-noli) J9333
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.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (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)**

☐ **Vyvgart**

- ☐ 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

☐ **Rystiggo**

- ☐ Individual has a diagnosis of generalized myasthenia gravis (gMG); AND
- ☐ Documentation is provided that individual has ONE of the following:
  - ☐ A positive serologic test for the presence of anti-acetylcholine receptor antibodies (AchR-Ab+); OR
  - ☐ A positive serologic test for the presence of anti-muscle-specific tyrosine kinase (MuSK) antibodies;
- ☐ Individual has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IVa disease ; AND

☐ Documentation is provided that individual has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of at least 3 or higher; AND

☐ Documentation is provided that individual meets both of the following (A and B):

- ☐ Individual has had a trial and inadequate response or intolerance to an acetylcholinesterase inhibitor; OR
  - ☐ Individual is on a stable dose of an acetylcholinesterase inhibitor; OR
  - ☐ Individual has a contraindication to acetylcholinesterase inhibitors;
- ☐ Individual has had a trial and inadequate response or intolerance to one or more immunosuppressive agents (including but not limited to systemic corticosteroids or non-steroidal immunosuppressants); OR
  - ☐ Individual is on a stable dose of one or more immunosuppressive agents (including but not limited to systemic corticosteroids or non-steroidal immunosuppressants); OR
  - ☐ Individual has a contraindication to systemic corticosteroids and non-steroidal immunosuppressants;

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

_____

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

☐ Vyvgart

☐ Rystiggo

- ☐ Reduction in signs or symptoms that impact daily function;
- ☐ 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 – Myasthenia Gravis PA

Drug Name(s):

VYVGART	**EFGARTIGIMOD ALFA-FCAB**
RYSTIGGO	**ROZANOLIXIZUMAB-NOLI**

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

Rystiggo

- Myasthenia gravis, Generalized, anti-acetylcholine receptor or anti-muscle-specific tyrosine kinase antibody positive

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

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