RX.PA.078.MPC Vyvgart® (efgartigimod alfa-fcab) & Vyvgart Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc)

The purpose of this policy is to define the prior authorization process for Vyvgart® (efgartigimod alfa-fcab) and Vyvgart Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc).

Site of Service

Medications included in this criteria are subject to review under policy RX.PA.070.MPC: Site of Service – Outpatient Infusion/Injection Services

PROCEDURE

A. Initial Authorization Criteria

	Products
Preferred	• **Vyvgart Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc)**
Non-preferred	• **Vyvgart ® (efgartigimod alfa-fcab)**

- For requests for non-preferred products, must have documented trial and failure or intolerance or contraindication to ALL preferred product(s).

1. Myasthenia Gravis

- Must have a documented diagnosis of myasthenia gravis with laboratory results confirming an anti-acetylcholine receptor (AChR) antibody positive serology
- Must have a documented Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II to IV
- MG-ADL baseline score greater than or equal to 5
- Must be age 18 years or older
- Must have a trial and failure (at least 3 months), intolerance to, or contraindication to pyridostigmine

- Documented failed treatment to azathioprine (at least 3 months) and at least one other immunosuppressive therapy or contraindication/intolerance to ALL listed below:
  - Cyclosporine
  - Mycophenolate mofetil
  - Tacrolimus
  - Methotrexate
  - Cyclophosphamide
  - Note: If members are contraindicated/intolerant to azathioprine, must have documentation of a trial and failure (at least 3 months) of 2 immunosuppressive therapies listed.

- Must be prescribed by or in consultation with a neurologist
- Must not be used concurrently with other biologics or treatment of myasthenia gravis such as Rystiggo, Soliris, Ultomiris, Zilbrysq
- Must have documentation of an adequate trial of at least 3 months with Soliris and experienced an inadequate response/significant side effects/toxicity or have a contraindication to this treatment
- Requests for Vyvgart must have a trial and failure, intolerance to, or contraindication to preferred product of Vyvgart Hytrulo

2. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

- Must have a documented diagnosis of CIDP
- Must be 18 years of age or older
- Must be prescribed by a neurologist
- Must provide documentation of electrodiagnostic testing (an EMG report)
- Must have moderate-to-severe functional disability
- Must provide a baseline disability score (using a validated disability scale, such as I-RODs, ODSS, ONLS, or INCAT)
- Note: Requests for treatment of CIDP are for Vyvgart Hytrulo only

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Vyvgart & Vyvgart Hytrulo will be considered investigational or experimental for any other use and will not be covered.

D. <u>Reauthorization Criteria:</u>

<u>MPC Renewal:</u>

- Chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy
- Must be prescribed by or in consultation with a neurologist

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria)
- Provider has documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year
Place of Service	When Vyvgart/Vyvgart Hytrulo is administered at any place of service other than 011 and 012, the service will be reviewed for medical necessity. The place of service codes are outlined below.

Place of Service Code(s)	**Place of Service Name**	**Place of Service Description**
011	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
012	Home	Location, other than a hospital or other facility, where the patient receives care in a private residence.

APPLICABLE CODES:	
CODE	**DESCRIPTION**
J9332	Injection, efgartigimod alfa-fcab, 2mg
J9334	Injection, efgartigimod alfa, 2mg and hyaluronidase-qvfc

REFERENCES

1. Vyvgart [package insert]. Zwijnaarde, Belgium: Argenx BV; April 2025.
2. Vyvgart Hytrulo [package insert]. Zwijnaarde, Belgium: Argenx BV; April 2025.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual policy review	*02/2026*
Update to myasthenia gravis indication to require trial and failure with Soliris	*12/2025*
New Policy	*06/2025*