

5.99.026

---

|                    |                        |                              |                  |
|--------------------|------------------------|------------------------------|------------------|
| <b>Section:</b>    | Prescription Drugs     | <b>Effective Date:</b>       | January 1, 2026  |
| <b>Subsection:</b> | Miscellaneous Products | <b>Original Policy Date:</b> | January 28, 2022 |
| <b>Subject:</b>    | Vyvgart                | <b>Page:</b>                 | 1 of 7           |

---

**Last Review Date:** December 12, 2025

---

## Vyvgart

### Description

Vyvgart\* (efgartigimod alfa-fcab)

Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)

\*Product covered on the medical benefit only

---

### Background

Vyvgart (efgartigimod alfa-fcab) is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating immunoglobulin G (IgG) antibodies and serum AChR auto-antibody levels. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) is a coformulation of efgartigimod alfa and hyaluronidase. Hyaluronidase increases the permeability of the subcutaneous tissue by depolarizing hyaluronan (1-2).

### Regulatory Status

FDA-approved indications: (1-2)

Vyvgart is indicated for the treatment of:

- generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Vyvgart Hytrulo is indicated for the treatment of:

- adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.
- adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

---

|                    |                        |                              |                  |
|--------------------|------------------------|------------------------------|------------------|
| <b>Section:</b>    | Prescription Drugs     | <b>Effective Date:</b>       | January 1, 2026  |
| <b>Subsection:</b> | Miscellaneous Products | <b>Original Policy Date:</b> | January 28, 2022 |
| <b>Subject:</b>    | Vyvgart                | <b>Page:</b>                 | 2 of 7           |

---

Because Vyvgart/Vyvgart Hytrulo cause transient reduction in IgG levels, immunization with live-attenuated or live vaccines is not recommended during treatment with Vyvgart/Vyvgart Hytrulo (1-2).

Vyvgart is administered as an intravenous infusion over one hour once weekly for 4 weeks. Vyvgart Hytrulo for gMG is administered subcutaneously over approximately 20 to 90 seconds in cycles of once weekly injections for 4 weeks. Subsequent treatment cycles should be administered based on clinical evaluation (1-2).

Vyvgart Hytrulo for CIDP is administered subcutaneously over approximately 20 to 90 seconds as once weekly injections. If a scheduled injection is missed, Vyvgart Hytrulo may be administered up to 3 days after the scheduled time point (2).

Vyvgart/Vyvgart Hytrulo contain warnings regarding infections and hypersensitivity reactions. Patients should be monitored during administration and for either one hour (Vyvgart) or 30 minutes (Vyvgart Hytrulo) thereafter for clinical signs and symptoms of hypersensitivity reactions (1-2).

The ADAPT trial studied patients with generalized myasthenia gravis with a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of at least 5 with at least 50% of the score due to non-ocular symptoms (3).

The International Consensus Guidance for Management of Myasthenia Gravis recommends the use of chronic IVIG and immunosuppressants (4).

The safety and effectiveness of Vyvgart/Vyvgart Hytrulo in pediatric patients less than 18 years of age have not been established (1-2).

---

#### Related policies

Imaavy, Rystiggo, Soliris, Ultomiris, Zilbrysq

#### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Vyvgart/Vyvgart Hytrulo may be considered **medically necessary** if the conditions indicated below are met.

Vyvgart/Vyvgart Hytrulo may be considered **investigational** for all other indications.

---

|                    |                        |                              |                  |
|--------------------|------------------------|------------------------------|------------------|
| <b>Section:</b>    | Prescription Drugs     | <b>Effective Date:</b>       | January 1, 2026  |
| <b>Subsection:</b> | Miscellaneous Products | <b>Original Policy Date:</b> | January 28, 2022 |
| <b>Subject:</b>    | Vyvgart                | <b>Page:</b>                 | 3 of 7           |

---

## Prior-Approval Requirements

### Vyvgart and Vyvgart Hytrulo

**Age** 18 years of age and older

#### **Diagnosis**

Patient must have the following:

1. Myasthenia Gravis (gMG)

**AND ALL** of the following:

- a. Positive serologic test for anti-AChR antibodies
- b. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
- c. Documented baseline score of **ONE** of the following:
  - i. MG-Activities of Daily Living (MG-ADL) total score  $\geq 5$   
([https://solirisgmg.com/Content/solirisgmg\\_com/assets/pdf/MG\\_ADL\\_Assessment.pdf](https://solirisgmg.com/Content/solirisgmg_com/assets/pdf/MG_ADL_Assessment.pdf))
  - ii. Quantitative Myasthenia Gravis (QMG) total score  $> 9$   
(<https://myasthenia.org/wp-content/uploads/Portals/0/QMG.pdf>)
- d. Patient has had an inadequate treatment response, intolerance, or contraindication to **ONE** of the following:
  - i. acetylcholinesterase inhibitor
  - ii. azathioprine
  - iii. cyclosporine
  - iv. mycophenolate mofetil
  - v. tacrolimus
  - vi. methotrexate
  - vii. cyclophosphamide
- e. IgG level  $\geq 6$  grams per liter (g/L)
- f. Prescriber agrees that the patient will be monitored during administration and for one hour after for clinical signs and symptoms of hypersensitivity reactions
- g. Absence of active infection (e.g., urinary tract infection or respiratory tract infection)

---

### Vyvgart Hytrulo only

|                    |                        |                              |                  |
|--------------------|------------------------|------------------------------|------------------|
| <b>Section:</b>    | Prescription Drugs     | <b>Effective Date:</b>       | January 1, 2026  |
| <b>Subsection:</b> | Miscellaneous Products | <b>Original Policy Date:</b> | January 28, 2022 |
| <b>Subject:</b>    | Vyvgart                | <b>Page:</b>                 | 4 of 7           |

---

**Age** 18 years of age and older

**Diagnosis**

Patient must have the following:

1. Chronic inflammatory demyelinating polyneuropathy (CIDP)

**AND ALL** of the following:

- a. IgG level  $\geq$  6 grams per liter (g/L)
- b. Prescriber agrees that the patient will be monitored during administration and for one hour after for clinical signs and symptoms of hypersensitivity reactions
- c. Absence of active infection (e.g., urinary tract infection or respiratory tract infection)

---

**Prior – Approval *Renewal* Requirements**

**Vyvgart and Vyvgart Hytrulo**

**Age** 18 years of age and older

**Diagnosis**

Patient must have the following:

1. Myasthenia Gravis (gMG)

**AND ALL** of the following:

- a. Decrease of MG-ADL or QMG total score from baseline of  $\geq$  2 points  
([https://solirisgmg.com/Content/solirisgmg\\_com/assets/pdf/MG\\_ADL\\_Assessment.pdf](https://solirisgmg.com/Content/solirisgmg_com/assets/pdf/MG_ADL_Assessment.pdf))  
(<https://myasthenia.org/wp-content/uploads/Portals/0/QMG.pdf>)
- b. At least 49 days have passed since the start of the previous treatment cycle
- c. Prescriber agrees that the patient will be monitored during administration and for one hour after for clinical signs and symptoms of hypersensitivity reactions
- d. Absence of active infection (e.g., urinary tract infection or respiratory tract infection)

---

**Vyvgart Hytrulo only**

---

|                    |                        |                              |                  |
|--------------------|------------------------|------------------------------|------------------|
| <b>Section:</b>    | Prescription Drugs     | <b>Effective Date:</b>       | January 1, 2026  |
| <b>Subsection:</b> | Miscellaneous Products | <b>Original Policy Date:</b> | January 28, 2022 |
| <b>Subject:</b>    | Vyvgart                | <b>Page:</b>                 | 5 of 7           |

---

**Age** 18 years of age and older

### Diagnosis

Patient must have the following:

1. Chronic inflammatory demyelinating polyneuropathy (CIDP)

**AND ALL** of the following:

- a. CIDP symptoms have remained stable or improved from baseline
- b. Prescriber agrees that the patient will be monitored during administration and for one hour after for clinical signs and symptoms of hypersensitivity reactions
- c. Absence of active infection (e.g., urinary tract infection or respiratory tract infection)

### Policy Guidelines

#### Pre – PA Allowance

None

#### Prior - Approval Limits

**Duration** 6 months

---

#### Prior – Approval *Renewal* Limits

**Duration** 12 months

### Rationale

#### Summary

Vyvgart and Vyvgart Hytrulo are used in the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. Vyvgart Hytrulo is also indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP). Patients should be monitored during administration and for one hour after for signs and symptom of hypersensitivity reactions. Vyvgart and Vyvgart Hytrulo contain warnings regarding infections and hypersensitivity reactions. The safety and effectiveness of

|                    |                        |                              |                  |
|--------------------|------------------------|------------------------------|------------------|
| <b>Section:</b>    | Prescription Drugs     | <b>Effective Date:</b>       | January 1, 2026  |
| <b>Subsection:</b> | Miscellaneous Products | <b>Original Policy Date:</b> | January 28, 2022 |
| <b>Subject:</b>    | Vyvgart                | <b>Page:</b>                 | 6 of 7           |

Vyvgart/Vyvgart Hytrulo in pediatric patients less than 18 years of age have not been established (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Vyvgart/Vyvgart Hytrulo while maintaining optimal therapeutic outcomes.

### References

1. Vyvgart [package insert]. Boston, MA: Argenx US, Inc.; October 2025.
2. Vyvgart Hytrulo [package insert]. Boston, MA: Argenx US, Inc.; October 2025.
3. Howard JF, Bril V, et al. Safety, efficacy, and tolerability of efgartigimod in patients with generalized myasthenia gravis (ADAPT): a multicentre, randomized, placebo-controlled, phase 3 trial. *Lancet Neurol.* 2021 Aug;20(8):e5.
4. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. *Neurology.* 2016; 87(4):419. Epub 2016 Jun 29.

### Policy History

| Date           | Action                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| January 2022   | Addition to PA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| March 2022     | Annual review and reference update. Per SME, added requirement of "absence of active infection" and added initiation requirement that for the MG-ADL score of 5, at least 50% of the score must come from non-ocular symptoms.                                                                                                                                                                                                                                                                        |
| December 2022  | Annual editorial review. Revised to align with BCBS association policy, removed initiation requirement of t/f of chronic IVIG, added requirement to t/f an acetylcholinesterase inhibitor, added requirement that patient have IgG level $\geq 6$ g/L. Revised continuation criterion to specify a decrease of MG-ADL of $\geq 2$ points. Approval limits for initiation and continuation changed to 6 months and 12 months, respectively. Quantity limits removed. Changed policy number to 5.99.026 |
| August 2023    | Addition of Vyvgart Hytrulo to policy                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| September 2023 | Annual review. Association policy alignment: removed requirement that at least 50% of MG-ADL score due to non-ocular symptoms, removed requirement that live vaccines not be given concurrently                                                                                                                                                                                                                                                                                                       |
| December 2023  | Annual review                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| June 2024      | Annual review and reference update                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| July 2024      | Per PI update, added indication of CIDP for Vyvgart Hytrulo                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| September 2024 | Annual review                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

|                    |                        |                              |                  |
|--------------------|------------------------|------------------------------|------------------|
| <b>Section:</b>    | Prescription Drugs     | <b>Effective Date:</b>       | January 1, 2026  |
| <b>Subsection:</b> | Miscellaneous Products | <b>Original Policy Date:</b> | January 28, 2022 |
| <b>Subject:</b>    | Vyvgart                | <b>Page:</b>                 | 7 of 7           |

---

|                |                                                                                                                               |
|----------------|-------------------------------------------------------------------------------------------------------------------------------|
| December 2024  | Annual review and reference update                                                                                            |
| June 2025      | Annual review and reference update                                                                                            |
| September 2025 | Per SME, removed double step requirement to t/f immunosuppressive therapy and added QMG score as an optional gMG scoring tool |
| December 2025  | Annual review and reference update                                                                                            |

## [Keywords](#)

---

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.**