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5.99.026

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Miscellaneous Products	**Original Policy Date:**	January 28, 2022
Subject:	Vyvgart	**Page:**	1 of 5

Last Review Date: December 8, 2023

Vyvgart

Description

Vyvgart (efgartigimod alfa-fcab)

Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)

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: Vyvgart and Vyvgart Hytrulo are indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive (1-2).

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 is administered subcutaneously over approximately 30 to 90 seconds in cycles of once weekly injections for 4 weeks. Subsequent treatment cycles should be administered

based on clinical evaluation. The safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established (1-2).

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
Soliris

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.

Prior-Approval Requirements

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 MG-Activities of Daily Living (MG-ADL) total score ≥ 5 (*https://solirisgmg.com/Content/solirisgmg_com/assets/pdf/MG_ADL_Assessment.pdf*)
d. Patient has had an inadequate treatment response, intolerance, or contraindication to acetylcholinesterase inhibitor and at least **ONE** immunosuppressive therapy either in combination or as monotherapy, such as:
    i. azathioprine
    ii. cyclosporine
    iii. mycophenolate mofetil
    iv. tacrolimus
    v. methotrexate
    vi. cyclophosphamide
e. IgG level ≥ 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)

Prior – Approval *Renewal* Requirements

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 total score from baseline of ≥ 2 points (*https://solirisgmg.com/Content/solirisgmg_com/assets/pdf/MG_ADL_Assessment.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)

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. 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 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.; April 2022.
2. Vyvgart Hytrulo [package insert]. Boston, MA: Argenx US, Inc.; June 2023.
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 ≥ 6 g/L. Revised continuation criterion to specify a decrease of MG-ADL of ≥ 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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.