CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines:
Medical Benefit Drugs

Vyvgart® (efgartigimod alfa-fcab) and Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)

Effective: December 1, 2023

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration-Approved Indications

Vyvgart (efgartigimod alfa-fcab) is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-gvfc) is a combination of efgartigimod alfa, a neonatal Fc receptor blocker, and hyaluronidase, an endoglycosidase, indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Vyvgart or Vyvgart Hytrulo for Members when all of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of generalized myasthenia gravis

AND

2. Documentation of a positive serologic test for anti-acetylcholine antibodies

AND

3. The prescribing physician is a neurologist

Reauthorization Criteria

1. Documented diagnosis of generalized myasthenia gravis

AND

2. Documentation of a positive serologic test for anti-acetylcholine antibodies

AND

3. The prescribing physician is a neurologist

AND

4. Documentation the Member has experienced a therapeutic response as defined by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline

Limitations

- Initial coverage of Vyvgart/Vyvgart Hytrulo for generalized myasthenia gravis will be authorized for 6 months. Reauthorization of Vyvgart/Vyvgart Hytrulo will be provided for 12-month intervals.
- Members new to the plan stable on Vyvgart/Vyvgart Hytrulo should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9332	Injection, efgartigimod alfa-fcab, 2 mg

References

1. Vyvgart (efgartigimod alfa-fcab). [package insert]. Boston, MA: argenx US, Inc.; Dec 2021.
2. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) [package insert]. Boston, MA: argenx US, Inc.; June 2023.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- September 12, 2023: Added Vyvgart Hytrulo to the Medical Necessity Guideline. Updated the title of the Medical Necessity Guideline from “Vyvgart” to “Vyvgart and Vyvgart Hytrulo.” Added Reauthorization Criteria, removed age requirements, added provider specialty requirements, and updated requirements for seropositive disease to read “Documentation of a positive serologic test for anti-acetylcholine antibodies.” Removed the Limitation “Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan.” (effective 12/1/23).

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.