

Medical Policy Manual **Draft Revised Policy: Do Not Implement**

Efgartigimod Alfa-fcab (Vyvgart®); Efgartigimod Alfa-fcab and Hyaluronidase-qvfc (Vyvgart®Hytrulo)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

**The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY**

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

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:

- A. Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.
- B. Adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP).

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. For initial requests, chart notes, medical records, or claims history documenting:
 - 1. Generalized myasthenia gravis:
 - i. Positive anti-acetylcholine receptor (AChR) antibody test
 - ii. Myasthenia Gravis Foundation of America (MGFA) clinical classification
 - iii. MG activities of daily living score
 - iv. Previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reasons to avoid therapy.
 - 2. Chronic inflammatory demyelinating polyneuropathy:
 - i. Electrodiagnostic testing (e.g., electromyography (EMG), nerve conduction studies (NCS))
 - ii. Previous therapies tried (e.g., immunoglobulins, corticosteroids, or plasma exchange), including response to therapy. If therapy is not advisable, documentation of clinical reasons to avoid therapy.
- B. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

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III. CRITERIA FOR INITIAL APPROVAL

A. Generalized myasthenia gravis (gMG)

Authorization of 6 months may be granted for treatment of generalized myasthenia gravis (gMG) when all of the following criteria are met:

1. Anti-acetylcholine receptor (AChR) antibody positive
2. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV
3. MG activities of daily living (MG-ADL) total score of greater than or equal to 5
4. Meets one of the following:
 - i. Member has had an inadequate response or intolerable adverse event to at least two immunosuppressive therapies over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, tacrolimus)
 - ii. Member has had an inadequate response or intolerable adverse event to at least one immunosuppressive therapy and intravenous immunoglobulin (IVIG) over the course of at least 12 months
 - iii. Member has a documented clinical reason to avoid therapy with immunosuppressive agents and IVIG
5. The requested medication will not be used in combination with another neonatal Fc receptor blocker (e.g., Rystiggo) or complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq)

B. Chronic inflammatory demyelinating polyneuropathy (CIDP) (Vyvgart Hytrulo Only)

Authorization of 6 months may be granted for treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) when all of the following criteria are met:

1. Disease course is progressive or relapsing/remitting for 2 months or longer
2. Diagnosis was confirmed by electrodiagnostic testing (consistent with EFNS/PNS guidelines)
3. Meets one of the following:
 - i. Member has had an inadequate response or intolerable adverse event to immunoglobulins, corticosteroids, or plasma exchange
 - ii. Member has a documented clinical reason to avoid therapy with immunoglobulins, corticosteroids, or plasma exchange

IV. CONTINUATION OF THERAPY

A. Generalized myasthenia gravis (gMG)

Authorization of 12 months may be granted for continued treatment of generalized myasthenia gravis (gMG) in members requesting reauthorization when all of the following criteria are met:

1. There is no evidence of unacceptable toxicity or disease progression while on the current regimen
2. Member demonstrates a positive response to therapy (e.g., improvement in MG-ADL score, MG Manual Muscle Test (MMT), MG Composite)
3. The requested medication will not be used in combination with another neonatal Fc receptor blocker (e.g., Rystiggo) or complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq)

B. Chronic inflammatory demyelinating polyneuropathy (CIDP) (Vyvgart Hytrulo Only)

Authorization of 12 months may be granted for treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) when all of the following criteria are met:

1. There is no evidence of unacceptable toxicity or disease progression while on the current regimen
2. Member demonstrates a positive response to therapy (e.g., improvement in Inflammatory Rasch-built Overall Disability Scale (I-RODS), Inflammatory Neuropathy Cause and Treatment (INCAT) disability scale, Medical Research Council (MRC) Sum score, grip strength).



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MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Vyvgart (Efgartigimod alfa-fcab)	Generalized Myasthenia Gravis (gMG)	Route of Administration: Intravenous <120kg 10mg/kg every week for 4 weeks ≥120kg 1200mg every week for 4 weeks The safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.
Vyvgart Hytrulo PFS (Efgartigimod alf-Hyaluronidase-qvfc)	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	Route of Administration: Subcutaneous 1000/10,000mg-units every week
Vyvgart Hytrulo PFS (Efgartigimod alf-Hyaluronidase- qvfc)	Generalized Myasthenia Gravis (gMG)	Route of Administration: Subcutaneous 1000/10,000mg-units every week for 4 weeks The safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.
Vyvgart Hytrulo Vial (Efgartigimod alf-Hyaluronidase- qvfc)	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	Route of Administration: Subcutaneous 1008/11,200mg-units every week
Vyvgart Hytrulo Vial (Efgartigimod alf-Hyaluronidase- qvfc)	Generalized Myasthenia Gravis (gMG)	Route of Administration: Subcutaneous 1008/11,200mg-units every week for 4 weeks. The safety of initiating subsequent cycles sooner than 50 days from the start of the previous treatment cycle has not been established.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

This document has been classified as public information

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1. Vyvgart [package insert]. Boston, MA: Argenx US, Inc.; January 2024.
2. Vyvgart Hytrulo [package insert]. Boston, MA: Argenx US. Inc.; June 2024.
3. Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2021; 96 (3) 114-122.
4. Howard JF, Bril V, Vu T, et al. Safety, efficacy, and tolerability of efgartigimod in patients with generalised myasthenia gravis (ADAPT): a multicentre, randomised, placebo-controlled, phase 3 trial. *Lancet Neurol*. 2021. 20:526-536.
5. Barnett C, Herbelin L, Dimachkie MM, Barohn RJ. Measuring Clinical Treatment Response in Myasthenia Gravis. *Neurol Clin*. 2018 May;36(2):339-353.
6. Van den Bergh PY, Hadden RD, van Doorn PA, et al. European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of chronic inflammatory demyelinating polyradiculoneuropathy: report of a joint task force of the European Federation of Neurological Societies and the Peripheral Nerve Society - second revision. *Eur J Neurol*. 2021;28(11):3556-3583.

EFFECTIVE DATE

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