Reference number(s)
5108-A

Standard Medicare Part B Management Vyvgart-Vyvgart Hytrulo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vyvgart	efgartigimod alfa-fcab
Vyvgart Hytrulo	efgartigimod alfa and hyaluronidase-qvfc

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 Indications[1,2]

Vyvgart

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

Vyvgart Hytrulo

Vyvgart Hytrulo is indicated for the treatment of:

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

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Documentation

The following documentation must be available, upon request, for all submissions:

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

Coverage Criteria

Generalized Myasthenia Gravis (gMG)[1-5]

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

- Anti-acetylcholine receptor (AChR) antibody positive.
- Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV.
- MG activities of daily living (MG-ADL) total score of greater than or equal to 5.
- Meets one of the following:
  - 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).
  - 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.
  - Member has a documented clinical reason to avoid therapy with immunosuppressive agents and IVIG.
- 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).

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (Vyvgart Hytrulo Only)[2,6]

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

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

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Generalized Myasthenia Gravis (gMG)

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The member is receiving benefit from therapy (e.g., improvement in MG-ADL score, MG Manual Muscle Test (MMT), MG Composite).
- 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).

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (Vyvgart Hytrulo Only)

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The member is receiving benefit from 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).

Summary of Evidence

The contents of this policy were created after examining the following resources:

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

- The prescribing information for Vyvgart and Vyvgart Hytrulo.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- International consensus guidance for management of myasthenia gravis.
- 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.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Vyvgart and Vyvgart Hytrulo are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for the trial of immunosuppressive agents and IVIG before initiating therapy with Vyvgart and Vyvgart Hytrulo can be found in the 2020 update to the international consensus guidance for management of myasthenia gravis. The update was completed prior to the approval of several new myasthenia gravis agents; however, the guidance includes recommendations for initiating treatment with a complement inhibitor (eculizumab [Soliris]). The recommendations indicate that eculizumab should be considered in the treatment of severe, refractory myasthenia gravis (after trials of other immunotherapies have been unsuccessful in meeting treatment goals).

Currently there are no treatment guidelines or literature supporting the concomitant use of complement inhibitors (e.g., Soliris, Ultomiris, Zilbrysq) or neonatal Fc receptor blockers (e.g., Vyvgart, Vyvgart Hytrulo, Rystiggo) for the treatment of generalized myasthenia gravis.

Support for the requirement that chronic inflammatory demyelinating polyneuropathy (CIDP) disease course be progressive or relapsing/remitting for 2 months or longer can be found in the European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of chronic inflammatory demyelinating polyradiculoneuropathy.

Support for a trial of immunoglobulins, corticosteroids, or plasma exchange can be found in the European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of chronic inflammatory demyelinating polyradiculoneuropathy. The guidelines strongly recommend the use of immunoglobulins, corticosteroids, or plasma exchange as first line treatments for CIDP.

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

References

1. Vyvgart [package insert]. Boston, MA: Argenx US, Inc.; October 2024.
2. Vyvgart Hytrulo [package insert]. Boston, MA: Argenx US, Inc.: August 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.

© 2025 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.