AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Vyvgart and Vyvgart Hytrulo	Page:	1 of 3
Effective Date:	10/15/2025	Last Review Date:	9/19/2025

Applies to:	☒Illinois	☒New Jersey	☒Maryland	☒Florida Kids
	☒Pennsylvania Kids	☒Virginia	☒Kentucky PRMD	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Vyvgart and Vyvgart Hytrulo under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Vyvgart
Vyvgart Hytrulo

Policy/Guideline:

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.

Criteria for Initial Approval:

Generalized myasthenia gravis (gMG)
Authorization of 6 months may be granted for treatment of generalized myasthenia gravis (gMG) when ALL 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)

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 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

Criteria for Continuation of Therapy

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 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)

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 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)

Approval Duration and Quantity Restrictions:

Initial Approval: 6 months
Renewal Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

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.