AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Vyvgart	Page:	1 of 2
Effective Date:	10/1//2023	Last Review Date:	8/17/2023

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

Intent:

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

Description:

FDA-Approved Indication

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.

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. Positive anti-acetylcholine receptor (AChR) antibody test
   2. Clinical classification of myasthenia gravis score
   3. MG activities of daily living score
   4. Use of an acetylcholinesterase (AChE) inhibitor, steroid, or non-steroidal immunosuppressive therapy (NSIST)
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 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 5 or more with at least 50% of the score due to non-ocular symptoms

4. On a stable dose of at least one of the following:
   a. Acetylcholinesterase inhibitors (e.g., pyridostigmine)
   b. Steroids (at least 3 months of treatment)
   c. Nonsteroidal immunosuppressive therapy (NSIST) (at least 6 months of treatment) (e.g., azathioprine, mycophenolate mofetil)

Criteria for Continuation of Therapy

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and member demonstrates a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in Quantitative Myasthenia Gravis (QMG) total score).

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 6 months

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

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. 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.