AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Vyvgart	Page:	1 of 2
Effective Date:	5/25/2023	Last Review Date:	3/15/2023

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

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 is 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

Policy/Guideline:

I. Criteria for Initial Approval:

A. Generalized myasthenia gravis

Authorization may be granted for generalized myasthenia gravis when chart notes, medical records, or claims history document 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 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 (at least 6 months of treatment) (e.g., azathioprine, mycophenolate mofetil)

II. Criteria for Continuation of Therapy

Authorization may be granted for continued treatment when all the following criteria are met:

1. Chart notes or medical record documentation supporting that there is no evidence of unacceptable toxicity or disease progression while on the current regimen and the member demonstrates a positive response to therapy
   a. 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.; December 2021.
2. Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. Neurology. 2021; 96 (3) 114-122.
3. 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.