

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 30, 2022

Vygart™ (efgartigimod alfa-fcab)

LENGTH OF AUTHORIZATION: One month

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient must have a diagnosis of generalized myasthenia gravis (gMG).
- Patient is anti-acetylcholine receptor (AChR) antibody positive.
- Patient is on stable dose of myasthenia gravis therapy prior to Vygart (e.g., acetylcholinesterase inhibitor, steroids, or non-steroidal immunosuppressive therapies).
- Patient has IgG ≥ 6 g/L.

CONTINUATION OF THERAPY

- Patient must continue to meet the above criteria; **AND**
- Documentation of improved clinical response; **AND**
- Patient has not have experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Available as 400 mg in 20 mL (20 mg/mL) single-dose vial.
- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>