

Vyvgart® (efgartigimod alfa-fcab) (Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 600 billable units weekly for 4 doses every 28 days

III. Initial Approval Criteria

Target Agent(s) will be approved when ALL of the following are met:

- ONE of the following:
 - The member has a diagnosis of generalized Myasthenia Gravis (gMG) AND ALL of the following:
 - The member has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb; **AND**
 - The member has a MG-Activities of Daily Living total score of greater than or equal to 5; **AND**
 - ONE of the following:
 - The member's current medications have been assessed and any medications known to exacerbate myasthenia gravis (e.g., beta blockers, procainamide, quinidine, magnesium, anti-programmed death receptor-1 monoclonal antibodies, hydroxychloroquine, aminoglycosides) have been discontinued; **OR**
 - Discontinuation of the offending agent is NOT clinically appropriate; **AND**
 - ONE of the following:
 - The member has tried and had an inadequate response to at least ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**

- The member has an intolerance or hypersensitivity to ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
- The member has an FDA labeled contraindication to ALL conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide); **OR**
- The member required chronic intravenous immunoglobulin (IVIG); **OR**
- The member required chronic plasmapheresis/plasma exchange; **AND**
- The member will NOT be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Soliris (eculizumab), Bkernv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Zilbrysq (zilucoplan), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), or Imaavy (nipocalimab-aahu); **OR**
- The member has another FDA labeled indication for the requested agent and route of administration; **AND**
- If the member has an FDA labeled indication, then ONE of the following:
 - The member's age is within FDA labeling for the requested indication for the requested agent; **OR**
 - There is support for using the requested agent for the member's age for the requested indication; **AND**
- The prescriber is a specialist in the area of the member's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the member's diagnosis; **AND**
- The member does NOT have any FDA labeled contraindications to the requested agent

IV. Renewal Criteria

Target Agent(s) will be approved when ALL of the following are met:

- The member has been previously approved for the requested agent through the plan's Prior Authorization process (Note: members not previously approved for the requested agent will require initial evaluation review); **AND**
- The member has had clinical benefit with the requested agent; **AND**
- The prescriber is a specialist in the area of the member's diagnosis (e.g., neurologist), or the prescriber has consulted with a specialist in the area of the member's diagnosis; **AND**
- The member will NOT be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Soliris (eculizumab), Bkernv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Zilbrysq (zilucoplan), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), or Imaavy (nipocalimab-aahu); **AND**

- The member does NOT have any FDA labeled contraindications to the requested agent

V. Dosage/Administration

Indication	Dose
Generalized Myasthenia Gravis (gMG)	Administer 10 mg/kg as an intravenous infusion over one hour once weekly for 4 weeks. In members weighing 120 kg or more, the recommended dose of Vyvgart is 1200 mg (3 vials) per infusion. **NOTE: Administer subsequent treatment cycles based on clinical evaluation, but no sooner than 7 days from the last administration of the previous treatment cycle.

VI. Billing Code/Availability Information

HCPCS Code:

- J9332 – Injection, efgartigimod alfa-fcab, 2 mg; 1 billable unit = 2 mg

NDC:

- Vyvgart 400 mg/20 mL single-dose vial: 73475-3041-xx

VII. References

1. Vyvgart prescribing information. Argenx US, Inc. May 2026.
2. National Institute of Neurological Disorders and Stroke. Myasthenia Gravis Fact Sheet. NIH Publication No. 17-768. July 2018.
3. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis. Neurology. 2021;96(3):114-122. doi:10.1212/wnl.00000000000011124.
4. Wincentzen J. MG Activities of Daily Living (MG-ADL) scale. Conquer Myasthenia Gravis. Published September 29, 2022. <https://myastheniagravis.org/mg-activities-of-daily-living-mg-adl-scale/>.
5. Alhaidar MK, Abumurad S, Soliven B, Rezania K. Current treatment of myasthenia gravis. Journal of Clinical Medicine. 2022;11(6):1597. doi:10.3390/jcm11061597.
6. Jayam Trough A, Dabi A, Solieman N, Kurukumbi M, Kalyanam J. Myasthenia gravis: a review. Autoimmune Dis. 2012;2012:874680. doi:10.1155/2012/874680.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan.

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Medical Necessity Criteria

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These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC