

## Clinical Policy: Efgartigimod Alfa-fcab (Vyvgart)

Reference Number: PA.CP.PHAR.555

Effective Date: 09/2022

Last Review Date: 01/2023

[Revision Log](#)

### Description

Efgartigimod alfa-fcab (Vyvgart<sup>®</sup>) is a neonatal Fc receptor (FcRn) antagonist.

### FDA Approved Indication(s)

Vyvgart is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness<sup>®</sup> that Vyvgart is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Generalized Myasthenia Gravis (must meet all):

1. Diagnosis of gMG;
2. Prescribed by or in consultation with a neurologist;
3. Age  $\geq$  18 years;
4. Myasthenia Gravis-Activities of Daily Living (MG-ADL) score  $\geq$  5 at baseline;
5. Greater than 50% of the baseline MG-ADL score is due to non-ocular symptoms;
6. Myasthenia Gravis Foundation of America (MGFA) clinical classification of Class II to IV;
7. Member has positive serologic test for anti-AChR antibodies;
8. Failure of a cholinesterase inhibitor (see Appendix B), unless contraindicated or clinically significant adverse effects are experienced;
9. Failure of a corticosteroid (see Appendix B), unless contraindicated or clinically significant adverse effects are experienced;
10. Failure of at least one immunosuppressive therapy (see Appendix B), unless clinically significant adverse effects are experienced or all are contraindicated;
11. Vyvgart is not prescribed concurrently with Soliris<sup>®</sup> or Ultomiris<sup>®</sup>;
12. Documentation of member's current weight (in kg);
13. Dose does not exceed 10 mg/kg (1,200 mg per infusion for members weighing 120 kg or more) once weekly for the first 4 weeks of every 8-week cycle.

**Approval duration: 6 months**

##### B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

**II. Continued Therapy**

**A. Generalized Myasthenia Gravis (must meet all):**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy as evidenced by a 2-point reduction in MG-ADL total score;
3. Vyvgart is not prescribed concurrently with Soliris or Ultomiris;
4. Documentation of member’s current weight (in kg);
5. If request is for a dose increase, new dose does not exceed 10 mg/kg (1,200 mg per infusion for members weighing 120 kg or more) once weekly for the first 4 weeks of every 8-week cycle.

**Approval duration: 6 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies .

**Approval duration: Duration of request or 6 months (whichever is less); or**

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53;**

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

AChR: acetylcholine receptor	MG-ADL: Myasthenia Gravis-Activities of Daily Living
FcRn: neonatal Fc receptor	MGFA: Myasthenia Gravis Foundation of America
FDA: Food and Drug Administration	
gMG: generalized myasthenia gravis	
IgG: immunoglobulin G	

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<b>Corticosteroids</b>		
betamethasone	Oral: 0.6 to 7.2 mg PO per day	7.2 mg/day
dexamethasone	Oral: 0.75 to 9 mg/day PO	9 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
methylprednisolone	Oral: 12 to 20 mg PO per day; increase as needed by 4 mg every 2-3 days until there is marked clinical improvement	40 mg/day
prednisone	Oral: 15 mg/day to 20 mg/day; increase by 5 mg every 2-3 days as needed	60 mg/day
<b>Cholinesterase Inhibitors</b>		
pyridostigmine (Mestinon®)	Oral immediate-release: 600 mg daily in divided doses (range, 60-1,500 mg daily in divided doses) Oral sustained release: 180-540 mg QD or BID	Immediate-release: 1,500 mg/day Sustained-release: 1,080 mg/day
neostigmine (Bloxiverz®)	Oral: 15 mg TID. The daily dosage should be gradually increased at intervals of 1 or more days. The usual maintenance dosage is 15-375 mg/day (average 150 mg) IM or SC: 0.5 mg based on response to therapy	Oral: 375 mg/day
<b>Immunosuppressants</b>		
azathioprine (Imuran®)	Oral: 50 mg QD for 1 week, then increase gradually to 2 to 3 mg/kg/day	3 mg/kg/day
mycophenolate mofetil (Cellcept®)*	Oral: Dosage not established. 1 gram BID has been used with adjunctive corticosteroids or other non-steroidal immunosuppressive medications	2 g/day
cyclosporine (Sandimmune®)*	Oral: initial dose of cyclosporine (non-modified), 5 mg/kg/day in 2 divided doses	5 mg/kg/day
Rituxan® (rituximab), Riabni™ (rituximab-arrx), Ruxience™ (rituximab-pvvr), Truxima® (rituximab-abbs)*†	IV: 375 mg/m <sup>2</sup> once a week for 4 weeks; an additional 375 mg/m <sup>2</sup> dose may be given every 1 to 3 months afterwards	375 mg/m <sup>2</sup>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

\*Off-label; †Prior authorization is required for rituximab products

#### Appendix C: Contraindications/Boxed Warnings

None reported

#### Appendix D: General Information

- The MG-ADL scale is an 8-item patient-reported scale that measures functional status in 8 domains related to MG – talking, chewing, swallowing, breathing, impairment of ability to brush teeth or comb hair, impairment of ability to arise from a chair, double vision, and eyelid droop. Each domain is given a score of 0-3, with 0 being normal and 3

being most severe impairment. A 2-point decrease in the MG-ADL score is considered a clinically meaningful response.

- In the Phase 3 ADAPT trial, all study patients received an initial 4-week treatment cycle of Vyvgart, with subsequent cycles administered according to individual clinical response when MG-ADL score was  $\geq 5$  (i.e., symptoms are at least the minimum threshold required for necessitating treatment) and, if the patient was an MG-ADL responder to the 4-week treatment cycle, when they no longer had a clinically meaningful decrease (MG-ADL clinically meaningful improvement defined as having  $\geq 2$ -point improvement in total MG-ADL score) compared with baseline. Subsequent cycles could commence no sooner than 8 weeks from initiation of the previous cycle.

### V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
gMG	10 mg/kg IV once weekly for the first 4 weeks of every 8-week cycle	10 mg/kg/week (1,200 mg per infusion for members weighing $\geq 120$ kg)

### VI. Product Availability

Single-dose vial: 400 mg/20 mL injection solution

### VII. References

1. Vyvgart Prescribing Information. Boston, MA: argenx US, Inc.; April 2022. Available at: <https://argenx.com/product/vyvgart-prescribing-information.pdf>. Accessed November 22, 2022.
2. Howard JF, Bril V, Vu T, et al. Safety, efficacy, and tolerability of efgartigimod in patients with generalized myasthenia gravis (ADAPT): a multicenter, randomised, placebo-controlled, phase 3 trial. *Lancet Neurology* July 2021;20(7):526-36.
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. *Neurology* 2016;87:419-425.
4. Narayanaswami P, Sanders DB, Wolfe G, et al. International consensus guidance for management of myasthenia gravis 2020 update. *Neurology* 2021;96:114-22.
5. Muppidi S, Silvestri N, Tan R, et al. The evolution of Myasthenia Gravis-Activities of Daily Living (MG-ADL) scale utilization to measure myasthenia gravis symptoms and treatment response (1817). *Neurology* Apr 2021;96(15 Suppl):1817.

### Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9332	Injection, efgartigimod alfa-fcab, 2 mg

**CLINICAL POLICY**  
Efgartigimod Alfa-fcab



Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08/2022	
1Q 2023 annual review: added to continuation of therapy requirement for no concurrent use with Soliris or Ultomiris; references reviewed and updated.	01/2023	