

**Clinical Policy: Efgartigimod Alfa-fcab, Efgartigimod/Hyaluronidase-qvfc
(Vyvgart, Vyvgart Hytrulo)**

Reference Number: LA.PHAR.555

Effective Date: 03.16.23

Last Review Date: ~~05.09.23~~05.02.24

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

Description

- Efgartigimod alfa-fcab (Vyvgart®) is a neonatal Fc receptor (FcRn) antagonist.
- Efgartigimod alfa/hyaluronidase-qvfc (Vyvgart® Hytrulo) is a combination of efgartigimod alfa, a neonatal Fc receptor blocker, and hyaluronidase, an endoglycosidase.

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FDA Approved Indication(s)

Vyvgart ~~is~~and Vyvgart Hytrulo are 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 Louisiana Healthcare Connections that Vyvgart ~~is~~and Vyvgart Hytrulo are 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 ≥ 18 years;
4. Myasthenia Gravis-Activities of Daily Living (MG-ADL) score ≥ 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~~The requested agent is not prescribed concurrently with Soliris® or Ultomiris®;

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12. For Vyvgart requests: Documentation of member's current weight (in kg);

13. Request meets one of the following (a or b):

13.a. Vyvgart: Dose does not exceed 10 mg/kg (1,200 mg per infusion for members weighing 120 kg or more) IV once weekly for the first 4 weeks of every 8-week cycle;

b. Vyvgart Hytrulo: Dose does not exceed 1,008 mg/11,200 units SC 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy: LA.PMN.53

II. Continued Therapy

A. Generalized Myasthenia Gravis (must meet all):

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by a 2-point reduction in MG-ADL total score;
3. Vyvgart-The requested agent is not prescribed concurrently with Soliris or Ultomiris;
4. For Vyvgart requests: Documentation of member's current weight (in kg);
5. If request is for a dose increase, new request meets one of the following (a or b):
 - a. Vyvgart: New dose does not exceed 10 mg/kg (1,200 mg per infusion for members weighing 120 kg or more) IV once weekly for the first 4 weeks of every 8-week cycle;
 - 5.b. Vyvgart Hytrulo: New dose does not exceed 1,008 mg/11,200 units SC 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy: LA.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 policy – LA.PMN.53 for Medicaid, or evidence of coverage documents.

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IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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

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
Corticosteroids		
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
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
Cholinesterase Inhibitors		
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
Immunosuppressants		
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™	IV: 375 mg/m ² once a week for 4 weeks; an additional 375 mg/m ² dose may be given every 1 to 3 months afterwards	375 mg/m ²

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
(rituximab-pvvr), Truxima® (rituximab-abbs)*†		

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 ≥ 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 ≥ 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/Drug Name	Dosing Regimen	Maximum Dose
<u>gMGEfgartigimod alfa-fcab (Vyvgart)</u>	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 ≥ 120 kg)
<u>Efgartigimod alfa/hyaluronidase-qvfc (Vyvgart Hytrulo)</u>	<u>1,008 mg efgartigimod alfa and 11,200 units hyaluronidase administered SC once weekly injections for the first 4 weeks of every 8-week cycle</u>	<u>1,008 mg/11,200 units per week</u>

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VI. Product Availability

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

Drug Name	Availability
<u>Efgartigimod alfa-fcab (Vyvgart)</u>	<u>Single-dose vial: 400 mg/20 mL injection solution</u>

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Drug Name	Availability
Efgartigimod alfa-hyaluronidase-qvfc (Vyvgart Hytrulo)	Single-dose vial: 1,008 mg (efgartigimod alfa)/11,200 units (hyaluronidase)/5.6 mL

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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, 202229, 2023.
2. Vyvgart Hytrulo Prescribing Information. Boston, MA: argenx US, Inc.; June 2023. Available at: <https://www.argenx.com/product/vyvgart-hytrulo-prescribing-information.pdf>. Accessed November 29, 2023.
3. Howard JF, Bril V, Vu T, et al. Safety, efficacy, and tolerability of efgartigimod in patients with generalized myasthenia gravis (ADAPT): a multicenter, randomized, placebo-controlled, phase 3 trial. *Lancet Neurology* July 2021;20(7):526-36.
4. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. *Neurology* 2016;87:419-425.
5. Narayanaswami P, Sanders DB, Wolfe G, et al. International consensus guidance for management of myasthenia gravis 2020 update. *Neurology* 2021;96:114-22.
6. 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.

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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
<u>J9334</u>	<u>Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc</u>

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Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy	02.23	03.16.23
Updated criteria for other diagnoses/indications for initial and continued therapies. Updated verbiage for Appendix B.	06.26.23	<u>10.05.23</u>
<u>Annual review: Vyvgart Hytrulo added to policy. Added HCPCS code [J9334]</u>	<u>05.02.24</u>	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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