Clinical Policy Title:	efgartigimod alfa-fcab
Policy Number:	RxA.724
Drug(s) Applied:	Vyvgart™
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Vyvgart™ is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
efgartigimod alfa-fcab (Vyvgart™)	Myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive.	Weight less than 120 kg: 10 mg/kg intravenous infusion over 1 hour once weekly for 4 weeks. Weight 120 kg or greater: 1200 mg (3 vials) intravenous infusion over 1 hour once weekly for 4 weeks.	1200 mg once weekly

Dosage Forms

- Injection: 400 mg in 20 mL (20 mg/mL) single-dose vial.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Generalized Myasthenia Gravis (must meet all):

1. Diagnosis of acetylcholine receptor antibody-positive (AChR-Ab+) generalized myasthenia gravis (gGM);
2. Age ≥ 18 years or older;
3. Prescribed by or in consultation with a neurologist or rheumatologist;
4. Member has myasthenia gravis with generalized muscle weakness meeting the clinical criteria for diagnosis of MG as defined by the Myasthenia Gravis Foundation of America (MGFA) class II, III, IV;
5. Documentation supports member has myasthenia gravis activities of daily living (MG-ADL) score of at least 5 or higher;

6. Failure of at least one (1) conventional agents (a, b or c) at up to maximally indicated dose, unless contraindicated or clinical significant adverse effects are experienced:
   a. Acetylcholinesterase inhibitors (e.g., oral pyridostigmine);
   b. Immunosuppressants (e.g., glucocorticoids, nonsteroidal immunosuppressants);
   c. Immunomodulators (e.g., intravenous immunoglobulin (IVIG), plasma exchange);
7. Dose does not exceed the following:
   a. Weight less than 120 kg: 10 mg/kg intravenous infusion over 1 hour once weekly for 4 weeks;
   b. Weight 120 kg or greater: 1200 mg (3 vials) intravenous infusion over 1 hour once weekly for 4 weeks.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Generalized myasthenia gravis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy;
2. Member has experienced a prior clinical response to Vyvgart™ treatment as defined by the following (a or b):
   a. Reduction in signs or symptoms that impact daily function;
   b. Documentation supports at least a 2-point reduction in MG-ADL total score from pre-treatment baseline;
3. If the request for dose increase, new dose does not exceed one of the following (a or b):
   a. Weight less than 120 kg: 10 mg/kg intravenous infusion over 1 hour once weekly for 4 weeks.
   b. Weight 120 kg or greater: 1200 mg (3 vials) intravenous infusion over 1 hour once weekly for 4 weeks.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
AChR-Ab+: Acetylcholine receptor antibody-positive.
gGM: Generalized myasthenia gravis.
MGFA: Myasthenia Gravis Foundation of America.
MG-ADL: Myasthenia Gravis Activities of Daily Living.

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Soliris®	900 mg intravenous infusion every 7 days for the first 4 weeks, followed by a single dose of 1,200 mg intravenous infusion given 7 days after the fourth dose, and then 1,200 mg intravenous infusion every	1,200 mg intravenous infusion/dose

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	14 days.	
Rituxan®	Administered at a dose of 375 mg/m^2 every week for four consecutive weeks then monthly for 2 months* OR 750 mg/m^2 every 2 weeks for 1 month*	Refer to dosing regimen

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Must not be administered with live-attenuated or live vaccines during treatment.
- Hypersensitivity reactions, including rash, angioedema, and dyspnea, were observed in Vyvgart™ treated patients.
- Myasthenia Gravis Foundation of America Clinical Classification;

Table 1. Myasthenia Gravis Foundation of America Clinical Classification

Class	Description
Class I	Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal.
Class II	Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
Class III	Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
Class IV	Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
Class V	Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management.

References

1. Vyvgart™ Prescribing Information. Boston, MA: Argenx US, Inc; December 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761195s000lbl.pdf. Accessed February 9, 2022.
2. IPD Analytics Rx Insights_New Drug Review_ Vyvgart™ 12.2021. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Vyvgart. Accessed February 9, 2022.
3. Argenx. A Randomized, Double-Blind, Placebo-Controlled, multicenter Phase 3 Trial to Evaluate the Efficacy, Safety and Tolerability of Argx-113 in Patients with Myasthenia Gravis Having Generalized Muscle Weakness. clinicaltrials.gov; 2022. Available at: https://clinicaltrials.gov/ct2/show/NCT03669588. Accessed February 9, 2022.

4. Anderson D, Phan C, Johnston WS, Siddiqi ZA. Rituximab in refractory myasthenia gravis: a prospective, open-label study with long-term follow-up. Ann Clin Transl Neurol. 2016;3(7):552-555. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4931720/#:~:text=Rituximab%20was%20either%20administered%20at,2%20weeks%20for%201%20month. Accessed February 9, 2022.
5. Drug. Lexi-Drug. Lexicomp. Wolters Kluwer. Hudson, OH. Available at: http://online.lexi.com. Accessed February 09, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/09/2022	04/18/2022