Clinical Policy Title:	efgartigimod alfa-fcab
Policy Number:	RxA.724
Drug(s) Applied:	Vyvgart®
Original Policy Date:	04/18/2022
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

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. Trial and 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. Vyvgart® is not prescribed concurrently with Soliris® or Ultomiris®;
8. 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 the 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

References

1. 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 7, 2023.
2. 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 7, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/09/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.7: Updated to include new diagnostic criteria Vyvgart® is not prescribed concurrently with Soliris® or Ultomiris. 2. References were reviewed and updated.	02/07/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023