Pharmacy Drug Policy & Procedure

Policy Name:	Vyvgart (efgartigimod alfa)	Policy #:	3140P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Vyvgart and Vyvgart Hytrulo.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Vyvgart or Vyvgart Hytrulo under the specialty medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for Myasthenia Gravis

1.1 Diagnosis of generalized myasthenia gravis with positive serological test for anti-AChR antibodies

1.2 Documentation to support a Myasthenia Gravis Foundation of America Clinical Classification of II, III, or IV at the start of therapy

1.3 Documentation to support a Myasthenia Gravis-Activities of Daily Living Score (MG-ADL) score ≥5

1.4 Prescribed by or in consultation with a neurologist or physician that specializes in treatment of generalized myasthenia gravis

1.5 Trial, failure, or contraindication to conventional therapies (i.e. pyridostigmine, immunosuppressant therapies)

1.6 Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Vyvgart by both a pharmacist and medical director

2. Coverage Criteria for Chronic Inflammatory Demyelinating Polyneuropathy (Vyvgart Hytrulo only)

2.1 Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by progressive or relapsing motor or sensory impairment of more than one limb for more than 2 months

2.2 Age 18 years or older

2.3 Prescribed by or in consultation with a neurologist

2.4 Documented trial and failure, intolerance or contraindication to corticosteroids

2.5 Documented trial and failure, intolerance or contraindication to a formulary immune globulin product

3. Exclusion Criteria

3.1 Vyvgart will not be covered in addition to Rystiggo, Soliris or Ultomiris

3.2 Polyneuropathy of other causes

- Vyvgart Hytrulo is not supported in the treatment of polyneuropathy related to any other condition

4. Approval Period

4.1 Myasthenia Gravis

- Initial: one 4 week treatment cycle over 12 months
- Subsequent Approvals: one 4 week treatment cycle over 12 months with documentation of positive clinical response to therapy

4.2 CIDP:

- Initial: 12 months
- Subsequent Approvals: 12 months with documentation of positive clinical response to therapy

CPT Codes

HCPCS Codes

J9332	Injection, efgartigimod alfa-fcab, 2mg
J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc

References

1. Vyvgart (efgartigimod alfa) [prescribing information]. Boston, MA: Argenx US Inc; January 2024.
2. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase) [prescribing information]. Boston, MA: Argenx US Inc; June 2024.
3. Verschuuren J. New therapies for autoimmune myasthenia gravis. Lancet Neurol. 2023 May;22(5):368-369.
4. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. Neurology. 2021 Jan 19;96(3):114-122.
5. ADHERE clinical trial abstract presentation https://www.neurology.org/doi/10.1212/WNL-.0000000000206324

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