

efgartigimod alfa fcab (Vyvgart_Vyvgart Hytrulo)

HCPCS: J9332 Injection, efgartigimod alfa-fcab, 2mg (Vyvgart), J9334 Injection, efgartigimod alfa, 2mg and hyaluronidase-qvfc (Vyvgart Hytrulo)

LOB:	MCAL, OneCare (Medicare Part B)
Duration of Approval:	For dx MG: One treatment course (once weekly four doses) (New/COC) For dx CIDP: Six months (new); one year (COC)
Quantity Limit:	Per FDA-Approved/Compendia-Supported Dosing
MCG Available:	No
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

Vyvgart (efgartigimod alfa-fcab) injection

Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) subcutaneous (SQ) injection

PA CRITERIA FOR APPROVAL:**New Therapy**

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References) OR a compendia-supported (Drugdex or American Hospital Formulary Service [AHFS]) indication **AND**
2. The medication is prescribed or recommended by a neurologist or physical medicine and rehabilitation (PMR) specialist **AND**
3. **For diagnosis of generalized myasthenia gravis (gMG):** Member meets ALL the following (a-d):
 - a. Documentation showing member is positive for anti-acetylcholine receptor (AChR)
 - b. Documentation showing member meets Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
 - c. The member has a Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score of ≥ 5 (**Note:** Use [MG-ADL calculator](#) if needed)
 - d. The member is currently on standard treatment OR has a history of failure, contraindication or intolerance to two standard treatments such as acetylcholinesterase (AChE) inhibitor (e.g., pyridostigmine), corticosteroids (e.g., prednisone, prednisolone, methylprednisolone) or immunosuppressive agents (e.g., azathioprine, methotrexate, cyclosporine, tacrolimus, mycophenolate mofetil, cyclophosphamide)

OR

4. **For diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) (For Vyvgart Hytrulo Only):** Member meets ALL of the following (a-c):
 - a. Chart notes showing clinical presentation of progressive or relapsing motor sensory impairment for at least two months
 - b. Diagnosis is confirmed by electrodiagnostic testing showing evidence of motor nerves and sensory conduction abnormalities
 - c. The member has a history of failure, contraindication or intolerance to at least ONE of the following: corticosteroids (e.g., prednisone, prednisolone, methylprednisolone), intravenous immunoglobulin (IVIG) or plasma exchange
(**Note:** corticosteroids have off-label support for dx: CIDP based on peer-reviewed literature)

Continuation of Therapy

1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References) OR a compendia-supported (Drugdex or AHFS) indication **AND**
2. The medication is prescribed or recommended by a neurologist or physical medicine and rehabilitation (PMR) specialist **AND**

efgartigimod alfa fcab (Vyvgart_Vyvgart Hytrulo)

HCPCS: J9332 Injection, efgartigimod alfa-fcab, 2mg (Vyvgart), J9334 Injection, efgartigimod alfa, 2mg and hyaluronidase-qvfc (Vyvgart Hytrulo)

- Documentation showing response to therapy, such as reduction in neuromuscular sign and symptoms, improvement in daily functioning, improvement of objective scores compared to pretreatment baseline (e.g., MG-ADL or QMG scores for gMG)

OTHER INFORMATION:

HCPCS	Description	Brand name
J9332	Injection, efgartigimod alfa-fcab, 2 mg	Vyvgart
J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc	Vyvgart Hytrulo

REFERENCES:

- Vyvgart Hytrulo Prescribing Information. www.argenx.com/product/vyvgart-hytrulo-prescribing-information.pdf. 02/2026.
- Vyvgart Prescribing Information. argenx.com/content/dam/argenx-corp/products/vyvgart-prescribing-information.pdf. 10/2025
- Van den Bergh PYK, Hadden RDM, Bouche P, et al. European Federation of Neurological Societies/Peripheral Nerve Society Guideline on management of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint task force of the European Federation of Neurological Societies and the Peripheral Nerve Society — First Revision. European Journal of Neurology 2010. 17: 356-363. onlinelibrary.wiley.com/doi/epdf/10.1111/j.1468-1331.2009.02930.x
- Argenex US, Inc. An Efficacy and Safety Study of ARGX-113 in Patients with Myasthenia Gravis Who Have Generalized Muscle Weakness (ADAPT). clinicaltrials.gov/study/NCT03669588. NLM Identifier: NCT03669588.
- Argenex US, Inc. A Study to Assess the Safety and Efficacy of a Subcutaneous Formulation of Efgartigimod in Adults with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP, an Autoimmune Disorder That Affects the Peripheral Nerves) (ADHERE). clinicaltrials.gov/study/NCT04281472. NLM Identifier: NCT04281472.

P&T APPROVAL HISTORY

- August 2024 P&T Drug Review.

UMC Review: 5/2026