CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
BENEFIT TYPE	Vyvgart: Medical Vyvgart Hytrulo: Medical or Pharmacy
STATUS	Prior Authorization Required

Vyvgart, approved by the FDA in 2021, is indicated for the treatment of adults with generalized myasthenia gravis (gMG). Vyvgart is a first-in-class IgG1 antibody Fc fragment designed to reduce pathogenic IgG autoantibody levels by inhibiting IgG recycling via the neonatal Fc receptor (FcRn) and increasing IgG degradation. Vyvgart Hytrulo is a combination of efgartigamod and hyaluronidase for subcutaneous administration.

Myasthenia gravis is an autoimmune disorder affecting the neuromuscular junction. It is characterized by muscle weakness and fatigue. The cause is an antibody-mediated immunologic attack directed at proteins in the postsynaptic membrane of the neuromuscular junction, most commonly the acetylcholine receptor (90%). Autoantibodies attack the AChR, blocking or destroying the receptors and damaging the neuromuscular junction, which impairs neuromuscular transmission and prevents muscles from contracting, as acetylcholine is unable to activate its receptor.

Pyridostigmine, an acetylcholinesterase inhibitor, is the initial drug of choice prescribed for MG. If control is inadequate, immunosuppressive treatment is added. Other drugs are used in cases of severe or refractory MG or myasthenic crisis, which is an emergency.

Vyvgart Hytrulo is also approved for chronic inflammatory demyelinating polyneuropathy (CIDP), a rare autoimmune disorder characterized by progressive peripheral neuropathy with typical and atypical phenotypes. Demyelination manifests as weakness, numbness, paresthesia, and sensory ataxia.

Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) will be considered for coverage when the following criteria are met:

Generalized Myasthenia Gravis (gMG)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of MGFA class II-IV myasthenia gravis (see appendix); AND
4. Member has tried and failed at least 1 conventional therapy:
   A. pyridostigmine
   B. corticosteroid for at least 4 weeks
   C. non-steroid immunosuppressant (e.g., azathioprine) for at least 6 months.
5. **Dosage allowed/Quantity limit:**
   IV infusion (Vyvgart) or SubQ injection (Vyvgart Hytrulo) once weekly for 4 weeks (1 cycle).

   Vyvgart-- Weight <120 kg: 10 mg/kg; Weight 120 kg or greater: 1200 mg (3 vials)

QL: 12 vials per 28 days; (1 vial= 20 mL).

Vyvgart Hytrulo vial-- 1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase)
QL: 4 vials per 28 days
Vyvgart Hytrulo prefilled syringe (PFS)-- 1,000 mg / 10,000 units (1,000 mg efgartigimod alfa and 10,000 units hyaluronidase)
QL: 4 syringes per 28 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must document clinically meaningful improvement in symptom severity and daily functioning compared to pre-treatment baseline (e.g., improved MG-ADL or QMG scores); AND

If all the above requirements are met, the medication will be approved for an additional 12 months.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP): Vyvgart Hytrulo only

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of CIDP confirmed by electrodiagnostic studies (motor and sensory nerve conduction studies); AND
4. Member has had symptoms of motor weakness and/or sensory disturbances present for at least 2 months; AND
5. Member has impairment of activities of daily living due to disabling symptoms; AND
6. Member has tried and failed at least 2 of the following for at least 3 months each:
   a) Corticosteroid (oral or IV)
   b) Immune globulin (IVIG or SCIG)
   c) Plasma exchange; AND
7. Member does NOT have pure sensory atypical CIDP.
8. **Dosage allowed/Quantity limit:**
   Vyvgart Hytrulo vial-- 1,008 mg / 11,200 units (1,008 mg efgartigimod alfa and 11,200 units hyaluronidase) administered subcutaneously as once weekly injections.
   QL: 4 vials per 28 days
   Vyvgart Hytrulo prefilled syringe (PFS)-- 1,000 mg / 10,000 units (1,000 mg efgartigimod alfa and 10,000 units hyaluronidase) administered subcutaneously as once weekly injections.
   QL: 4 syringes per 28 days

If all the above requirements are met, the medication will be approved for 4 months.

For **reauthorization**:
1. Member has improvement of neuromuscular disability and impairment, with sustained stability since initiation of therapy.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
01/19/2022	New policy for Vyvgart created.
07/03/2023	Added Vyvgart Hytrulo to policy. Added reference. Split list of conventional drug trials. Added treatment cycle spacing to reauth.
06/24/2024	Added criteria for new CIDP indication.
04/16/2025	Added self-admin Vyvgart Hytrulo PFS formulation to policy; updated dosing and added pharmacy as benefit type option. MG: Changed steroid trial duration from 3 months to 4 weeks (Sanders, Alhaidar).
05/12/2026	MG: Removed restriction that subsequent cycles may take place no sooner than 50 days from the start of the previous cycle, per label update stating subsequent cycles are administered according to clinical evaluation. Removed requirement that member must be seropositive for AChR antibodies per label update.

Appendix:

MG Foundation of America (MGFA) Clinical Classification	
Class I	any ocular weakness; all other muscle strength is normal
Class II	mild weakness affecting other than ocular muscles; may also have ocular weakness at any level
Class III	moderate weakness affecting other than ocular muscles; may also have ocular weakness at any level
Class IV	severe weakness affecting other than ocular muscles; may also have ocular weakness at any level
Class V	defined by intubation, with or without mechanical ventilation

References:

1. Vyvgart [prescribing information]. argenx BV; 2026.
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4. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology*. 2021;96(3):114-122. doi:10.1212/WNL.0000000000011124
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6. Alhaidar MK, Abumurad S, Soliven B, Rezania K. Current Treatment of Myasthenia Gravis. *J Clin Med*. 2022;11(6):1597. Published 2022 Mar 14. doi:10.3390/jcm11061597
7. Ryan M, Ryan SJ. Chronic inflammatory demyelinating polyneuropathy: considerations for diagnosis, management, and population health. *Am J Manag Care*. 2018;24(17 Suppl):S371-S379.
8. Van den Bergh PYK, van Doorn PA, Hadden RDM, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint Task Force-Second revision [published correction appears in Eur J Neurol. 2022 Apr;29(4):1288 doi: 10.1111/ene.15225]. *Eur J Neurol*. 2021;28(11):3556-3583. doi:10.1111/ene.14959

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