Effective Date: 1/01/2026
Reviewed: 10/2025

VYVGART HYTRULO PREFILLED SYRINGE
(efgartigimod alfa and hyaluronidase-qvfc)

POLICY

*This policy does not apply to Vyvgart Hytrulo 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase per 5.6 mL (180 mg/2,000 units per mL) single-dose vials to be administered only by a healthcare professional. Dosing varies for vial compared with prefilled syringe. Refer to Vyvgart and Vyvgart Hytrulo policy on medical benefit.

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Vyvgart Hytrulo is indicated for the treatment of adult patients with:
1. Generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive
2. Chronic inflammatory demyelinating polyneuropathy (CIDP)

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

For all indications
All of the following criteria must be met in addition to indication-specific criteria below:
1. Member is ≥ 18 years of age
2. Prescribed by, or in consultation with, a neurologist
3. Only one formulation of efgartigimod will be used (intravenous or subcutaneous)
4. The member will not be using the requested agent in combination with other immunomodulatory biologic therapies (e.g., Imaavy (nipocalimab), Rystiggo (rozanolixizumab), Zilbrysq (zilucoplan), Soliris/Epysqli/Bkemv (eculizumab), Ultomiris (ravulizumab), etc.)
5. The member does NOT have any FDA labeled contraindications to the requested agent
6. The requested quantity (dose) is within FDA labeled dosing for the requested indication

Generalized myasthenia gravis (gMG)
Authorization of 6 months may be granted for the treatment of generalized myasthenia gravis (gMG) when all of the following criteria are met:
1. Documentation with medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG)

2. Documentation that member has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies
3. Documentation that member has Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II to IVb disease
4. Physician has assessed objective signs of neurological weakness and fatigability on a baseline neurological examination (e.g., including, but not limited to, the Quantitative Myasthenia Gravis (QMG) score or the MG-Activities of Daily Living (MG-ADL) score, etc.)
5. Documentation that member has a baseline MG-Activities of daily living (MG-ADL) total score ≥5
6. Documentation that member meets one of the following:
    a. The member has tried and had an inadequate response to at least ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide)
    b. The member has an intolerance or hypersensitivity to ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide)
    c. The member has an FDA labeled contraindication to ALL conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide)
    d. The member required chronic intravenous immunoglobulin (IVIG)
    e. The member required chronic plasmapheresis/plasma exchange
7. The member's current medications have been assessed and any medications known to exacerbate myasthenia gravis (e.g., beta blockers, procainamide, quinidine, magnesium, anti-programmed death receptor-1 monoclonal antibodies, hydroxychloroquine, aminoglycosides) have been discontinued **OR** discontinuation of the offending agent is NOT clinically appropriate

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Authorization of 6 months may be granted for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) when all of the following criteria are met:

1. Documentation that member's disease course is progressive or relapsing and remitting for at least 2 months
2. Documentation that member has progressive or relapsing motor sensory impairment of more than one limb
3. Documentation that diagnosis was confirmed by electrodiagnostic testing indicating demyelination with at least one of the following:
    a. Prolonged distal motor latency in at least 2 motor nerves
    b. Reduced motor conduction velocity in at least 2 motor nerves
    c. Prolonged F-wave latency in at least 2 motor nerves
    d. Absent F-wave in at least 2 motor nerves plus one other demyelination criterion listed here in at least 1 other nerve
    e. Partial motor conduction block in at least 2 motor nerves or in 1 nerve plus one other demyelination criterion listed here
    f. Abnormal temporal dispersion conduction in at least 2 motor nerves
    g. Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve

4. Documentation of baseline strength/weakness using an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.
5. Documentation that member has tried and had an inadequate response to at least a 3-month trial of or intolerance to ONE standard of care therapy (i.e., corticosteroids, immunoglobulins or plasma exchange therapy) or an FDA-labeled contraindication to ALL standard of care of therapies aforementioned
6. Will not be used as maintenance therapy in combination with immunoglobulin

III. CONTINUATION OF THERAPY

For all indications
All of the following criteria must be met in addition to indication-specific criteria below:

1. The member was previously approved for the requested drug through the plan's Pharmacy Drug Review process (Note: patients not previously approved for the requested agent will require initial evaluation review)
2. The requested agent continues to be prescribed by, or in consultation with, a neurologist
3. Only one formulation of efgartigimod will be used (intravenous or subcutaneous)
4. The member will not be using the requested agent in combination with other immunomodulatory biologic therapies (e.g., Imaavy (nipocalimab), Rystiggo (rozanolixizumab), Zilbrysq (zilucoplan), Soliris/Epysqli/Bkemv (eculizumab), Ultomiris (ravulizumab), immunoglobulin therapy, etc.)
5. The member does NOT have any FDA labeled contraindications to the requested agent
6. The requested quantity (dose) is within FDA labeled dosing for the requested indication

Generalized myasthenia gravis (gMG)

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization when the following criteria are met:

1. Documentation that member demonstrates a positive response to therapy by an improvement (i.e., reduction) of at least 2-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score sustained for at least 4-weeks ***Δ***
2. Documentation of improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline
3. Member requires continuous treatment, after an initial beneficial response, due to new or worsening disease activity (Note: Subsequent treatment cycles were administered NO sooner than 28 days from the last administration of the previous treatment cycle)

*(**Δ** May substitute an improvement of at least 3-points from baseline in the Quantitative Myasthenia Gravis (QMG) total score sustained for at least 4-weeks, if available)*

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
Authorization of 6 months may be granted for continued treatment in members requesting reauthorization when the following criteria are met:

1. Documentation that member has demonstrated a clinical response to therapy based on an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength, 6-MWT, Rankin, Modified Rankin, etc.)

IV. DOSAGE AND ADMINISTRATION

Indication	Dose
gMG	• Vyvgart Hytrulo* is supplied as single-dose 5 ml prefilled syringe containing 1,000 mg efgartigimod alfa and 10,000 units hyaluronidase (200 mg/2,000 units per mL) administered subcutaneously over approximately 20 to 30 seconds in cycles of once weekly injections for 4 weeks. • Administer subsequent treatment cycles based on clinical evaluation. • *Note: In clinical trials, subsequent treatment cycles were administered NO sooner than 28 days from the last administration of the previous treatment cycle.*
CIDP	• Vyvgart Hytrulo* is supplied as single-dose 5 ml prefilled syringe containing 1,000 mg efgartigimod alfa and 10,000 units hyaluronidase (200 mg/2,000 units per mL) administered subcutaneously over approximately 20 to 30 seconds as once weekly injections.

V. QUANTITY LIMIT

Vyvgart Hytrulo* 1000-10000 mg-unit/5ml: 4 syringes per 28 days (daily dose of 0.72 ml)

For gMG requests, coverage requests will be approved for 4 syringes per 56 days.

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VI. REFERENCES

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