Agile Infusion Services LLC
Web: www.AgileIV.com | Tel: (201) 751-2202 | Fax: (201) 266-0437 | Email: info@AgileIV.com

VYVGART or VYVGART HYTRULO MEDICATION ORDER

Please complete all attached pages and submit to My Vyvgart Path via fax at 833-698-7284.

Signatures by the patient and prescriber are required as indicated.

Completing all lines of the worksheet will significantly ease the authorization process. Once the case is transferred to us, we will contact your office to obtain supporting documentation.

Thank you!

VYVGART® Hytrulo
(efgartigimod alfa and hyaluronidase-qvfc)
Subcutaneous Injection
180 mg/mL and 2000 U/mL vial

VYVGART®
(efgartigimod alfa-fcab)
Injection for Intravenous Use
400 mg/20 mL vial

Enrollment Form

To enroll patients, fax the completed form to My VYVGART Path at **1-833-MY-V-PATH (1-833-698-7284)**. Visit **MyPathEnroll.com** for more information.
For questions, please contact My VYVGART Path at **1-833-VYVGART (1-833-898-4278)**.
Office hours: Monday through Friday, 8 AM to 8 PM ET.

***Indicates required field.**

1. PATIENT INFORMATION

***Patient First Name:**	***Patient Middle Initial:**
***Patient Last Name:**	
***DOB (MM/DD/YYYY):**	***Patient Email:**
***Phone #:**	Alternate Phone #:
***Patient Mailing Address:**	
***City:**	***State:** / ***Zip:**

Patient Gender: ☐ Male ☐ Female ☐ Nonbinary

Patient-Preferred Language: ☐ English ☐ Spanish ☐ Other _____

Is your patient new to VYVGART Hytrulo or VYVGART? ☐ Yes ☐ No

Authorized Caregiver or Alternate Contact: *By providing this information, you authorize My VYVGART Path to discuss the patient's health condition and participation in My VYVGART Path with the person named below.*

Caregiver First Name:	Caregiver Middle Initial:
Caregiver Last Name:	Relationship to Patient:
Caregiver Email:	Caregiver Phone Number:

2. INSURANCE INFORMATION

Please fax copies of both the front and back of all medical and prescription insurance cards.

Check here if the patient has no insurance: ☐

Co-Pay Program: ☐ Yes ☐ No

Patient Assistance Program : ☐ Yes ☐ No

	*Primary Benefit	Secondary Benefit	Pharmacy Benefit
***Insurance Name**			
***Policyholder Name:**			
***Policy ID #:**			
Relationship to Patient:			
Insurance Provider Phone #:			
Group #:			
PCN #:			
BIN #:			

3. PRESCRIBER INFORMATION

***Prescriber Name (First, Middle, Last):**

***Practice Name:**

*NPI #:	*Tax ID:	*State License #:	Medicare/Medicaid Provider #:

*Practice Address:	*City:	*State:	*Zip:

*Office Phone #:	*Office Fax #:	Prescriber Email:

Please provide direct contact information for an office contact who can handle access issues.

Office Contact Name:	Office Contact Phone #:	Office Contact Email:

For section 4. PRESCRIPTION INFORMATION, please complete either page 3 for generalized myasthenia gravis (gMG) or page 4 for chronic inflammatory demyelinating polyneuropathy (CIDP).

Patient Name: _____

4. ☐ *PRESCRIPTION INFORMATION: GENERALIZED MYASTHENIA GRAVIS (gMG)

*Patient First Name:	*Patient Middle Initial:	*Patient Last Name:	*DOB (MM/DD/YYYY):

*Site of Care Location: ☐ Prescribing physician's office ☐ Home injection ☐ Infusion center ☐ Hospital outpatient ☐ Patient's choice ☐ Specialty pharmacy ☐ Unknown

Preferred Site of Care Name:	Preferred Site of Care Address:
Specialty Pharmacy: ☐ Yes ☐ No	Preferred Specialty Pharmacy Name:
Buy and Bill: ☐ Yes ☐ No	Other Instructions:

*Primary Diagnosis ICD-10 Code: ☐ G70.00 (Myasthenia gravis without acute exacerbation) ☐ G70.01 (Myasthenia gravis with acute exacerbation)

*Anti-AChR Antibody Positive: ☐ Yes ☐ No

Patient Allergies:

Current Therapies: ☐ Treatment-naïve ☐ Mestinon ☐ Nonsteroidal ISTs ☐ Oral corticosteroids ☐ Zilucoplan ☐ Other ☐ Rituximab ☐ Eculizumab ☐ Rozanolixizumab ☐ Ravulizumab-cwvz ☐ IVIg

Previous Therapies: ☐ Treatment-naïve ☐ Mestinon ☐ Nonsteroidal ISTs ☐ Oral corticosteroids ☐ Zilucoplan ☐ Other ☐ Rituximab ☐ Eculizumab ☐ Rozanolixizumab ☐ Ravulizumab-cwvz ☐ IVIg

Current MG-ADL Score (Optional):_____
MG-ADL=Myasthenia Gravis Activities of Daily Living

MGFA Classification (Optional):_____
MGFA=Myasthenia Gravis Foundation of America

Please check for preferred VYVGART treatment. Complete the applicable prescription information section(s) based on this selection.

☐ VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection

VYVGART Hytrulo is a fixed dose per injection.

Dosing	**1,008 mg efgartigimod alfa and 11,200 units hyaluronidase per 5.6 mL (180 mg/2,000 units per mL) in a single-dose vial**
Directions	Administer subcutaneously over approximately 30 to 90 seconds once weekly for 4 weeks (4 once-weekly injections = 1 treatment cycle) with _____ weeks between treatment cycles.
Refills	***Number of Refills (Treatment Cycles) Authorized:** _____ (4 once-weekly injections = 1 treatment cycle)

☐ VYVGART (efgartigimod alfa-fcab) for intravenous use

VYVGART is weight based. For assistance, visit vyvgarthcp.com/dosing/vyvgart.

Dosing	**10 mg/kg x patient weight (kg) = dose (mg)** **Strength:** 400 mg/20 mL (20 mg/mL) in a 20 mL single-dose vial **Calculated Dose:** ***Patient Weight:** _____ **kg** *To convert from lb to kg, divide the patient's weight in lb by 2.205. For patients weighing 120 kg or more, the dose should not exceed 1,200 mg (3 vials) per infusion.* ☐ _____ **mg based on weight** ☐ **1,200 mg for patients greater than 120 kg**
Directions	Infuse once weekly for 4 weeks (4 once-weekly infusions = 1 treatment cycle) with _____ weeks between infusion cycles.
Refills	***Number of Refills (Treatment Cycles) Authorized:** _____ (4 once-weekly infusions = 1 treatment cycle)

Additional Instructions:

PRESCRIBER AUTHORIZATION AND ATTESTATION

By signing below, I certify that I am prescribing VYVGART Hytrulo or VYVGART for the patient identified herein, and that I have received permission from the patient and met other applicable requirements of the Health Insurance Portability and Accountability Act of 1996 and applicable state laws needed to release the information that I am providing in this enrollment form. I understand that such information may be used by My VYVGART Path, its designated agents, service providers, and dispensing pharmacies for the purposes of verifying the patient's insurance coverage for VYVGART Hytrulo or VYVGART, confirming prior authorization requirements for VYVGART Hytrulo or VYVGART, if needed, on my patient's behalf, providing information to my office or the patient on appeals of denials of claims, coordinating delivery of VYVGART Hytrulo or VYVGART, and providing my patient with other education and support. I authorize My VYVGART Path, its affiliates, agents, and contractors to act on my behalf for the limited purposes of transmitting this prescription, by any means allowed under applicable law, to the appropriate pharmacy designated by the patient utilizing their benefit plan.
ATTN: New York and Iowa providers, please submit an electronic prescription.

"Dispense As Written"/Brand Medically Necessary/Do Not Substitute/No Substitution/DAW/May Not Substitute

*Prescriber Signature: _____ *Date (MM/DD/YYYY): _____

4. ☐ *PRESCRIPTION INFORMATION:
CHRONIC INFLAMMATORY DEMYELINATING POLYNEUROPATHY (CIDP)

VYVGART Hytrulo only

***Patient First Name:**	***Patient Middle Initial:**
***Patient Last Name:**	***DOB (MM/DD/YYYY):**

***Site of Care Location:** ☐ Prescribing physician's office ☐ Home injection ☐ Infusion center ☐ Hospital outpatient ☐ Patient's choice ☐ Specialty pharmacy ☐ Unknown

Preferred Site of Care Name: Agile Infusion Services - Tel (201) 751-2202	Preferred Site of Care Address: Whichever the patient prefers. See www.AgileIV.com for sites.
Specialty Pharmacy: ☐ Yes ☑ No	Preferred Specialty Pharmacy Name: If insurance carrier requires a specialty pharmacy to Buy & Bill, it will direct the specific SP.
Buy and Bill: ☑ Yes ☐ No	Other Instructions: Agile Infusion's intake staff will coordinate these services with the prescriber and patient.

***Primary Diagnosis ICD-10 Code:** ☐ G61.81	Patient Allergies:

Current Therapies: ☐ Treatment-naïve ☐ IVIg ☐ Corticosteroids ☐ SCIg ☐ Other

Previous Therapies: ☐ Treatment-naïve ☐ IVIg ☐ Corticosteroids ☐ SCIg ☐ Other

☐ **VYVGART Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) for subcutaneous injection**

VYVGART Hytrulo is a fixed dose per injection.

Dosing	**1,008 mg efgartigimod alfa and 11,200 units hyaluronidase per 5.6 mL (180 mg/2,000 units per mL) in a single-dose vial**
Directions	Administer subcutaneously over approximately 30 to 90 seconds once weekly.
Refills	***Dispense Quantity:** _____ *(Dispensed as single-dose vials)* ***Refills:** _____

Additional Instructions:

PRESCRIBER AUTHORIZATION AND ATTESTATION

By signing below, I certify that I am prescribing VYVGART Hytrulo for the patient identified herein, and that I have received permission from the patient and met other applicable requirements of the Health Insurance Portability and Accountability Act of 1996 and applicable state laws needed to release the information that I am providing in this enrollment form. I understand that such information may be used by My VYVGART Path, its designated agents, service providers, and dispensing pharmacies for the purposes of verifying the patient's insurance coverage for VYVGART Hytrulo, confirming prior authorization requirements for VYVGART Hytrulo, if needed, on my patient's behalf, providing information to my office or the patient on appeals of denials of claims, coordinating delivery of VYVGART Hytrulo, and providing my patient with other education and support. I authorize My VYVGART Path, its affiliates, agents, and contractors to act on my behalf for the limited purposes of transmitting this prescription, by any means allowed under applicable law, to the appropriate pharmacy designated by the patient utilizing their benefit plan.

ATTN: New York and Iowa providers, please submit an electronic prescription.

"Dispense As Written"/Brand Medically Necessary/Do Not Substitute/No Substitution/DAW/May Not Substitute

***Prescriber Signature:** _____ ***Date (MM/DD/YYYY):** _____

5. PATIENT AUTHORIZATION TO COLLECT, USE, AND DISCLOSE PROTECTED HEALTH INFORMATION

By signing below, I authorize my healthcare providers, pharmacies, and health plans (collectively, my "Health Team") to: disclose my personal health information ("PHI"), including my medical condition, prescription, and insurance coverage, to argenx, its affiliates, contractors, and agents, in order for them to use and share with my Health Team as needed to enroll me in My VYVGART Path; conduct benefits investigations and take related actions to determine my eligibility for, and coordinate financial assistance for me to receive VYVGART Hytrulo or VYVGART; communicate with my Health Team about my treatment plan; provide me with support services, including disease state and VYVGART Hytrulo or VYVGART education and resources; help facilitate prescription and refill fulfillment; facilitate quality control and related reporting activities; use my de-identified data for research and publication; conduct data analytics, market research, and My VYVGART Path–related business activities; and/or contact me about My VYVGART Path services. I understand that once my PHI has been disclosed to argenx, it may no longer be protected by federal privacy law and could be re-disclosed to others; I can withdraw this authorization by calling 833-697-2841 or mailing notice of revocation to My VYVGART Path, 680 Century Point, Suite 1000, Lake Mary, FL 32746; revocation will take effect when My VYVGART Path receives my notice of revocation, but uses and disclosures made in reliance on the authorization prior to its revocation will not be invalidated; my healthcare treatment, payment for treatment, insurance enrollment, or eligibility for insurance benefits are not conditioned upon my signing this authorization; this authorization expires 10 years after signing or on such earlier date as state law may require and I am entitled to receive a copy of this authorization after I sign it. A disclosing party may receive remuneration in exchange for PHI if our relationship involves receipt of compensation in exchange for data or in connection with providing PHI pursuant to an authorization. I understand that I am entitled to submit a written request to argenx for a copy of this consent language, along with any disclosed PHI. I further authorize argenx to contact any individual(s) identified as an Authorized Caregiver (below) to discuss my medical condition or my participation in My VYVGART Path, and I understand that such discussions may require argenx to disclose my PHI to such Authorized Caregiver.

***Patient Name:**	***DOB (MM/DD/YYYY):**
***Patient Signature:**	***Date Signed (MM/DD/YYYY):**

Authorized Caregiver Name and Phone #:

☐ *Check here to receive patient education program information, engagement communication requests from argenx, and emails promoting argenx products and services.*

☐ *Check here to consent to mobile messaging promoting argenx products and services. Message and data rates may apply.*

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VYVGART or VYVGART HYTRULO MEDICATION ORDER

Patient's Name (Last, First, Middle) _____ DOB _____

Patient's height in feet and inches _____ *Patient's weight in pounds* _____

■ **Diagnosis**

☐ G70.00 Myasthenia gravis without (acute) exacerbation
☐ G70.01 Myasthenia gravis with (acute) exacerbation
☐ G61.81 Chronic Inflammatory Demyelinating Polyneuritis

■ **Details Needed for Approval** *Please answer all questions and provide supporting documentation.*

- Is the patient anti-acetylcholine receptor antibody positive (AChR-Ab+)? _____ *If yes, please provide results.*
- What Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of disease does the patient have? _____
- What is the score of the patient's Myasthenia Gravis Activities of Daily Living (MG-ADL)? _____
- What percentage of the MG-ADL score is due to non-ocular symptoms? _____
- Is the patient receiving a stable dose of ≥ 1 of acetylcholinesterase inhibitors, steroids or NSIST? _____ If yes, provide details.
- Which conventional therapies has the patient had an inadequate response to? _____
- Has the patient required chronic plasmapheresis or plasma exchange therapy also? _____
- Will the patient have concomitant treatment with rituximab, eculizumab or immunoglobulins? _____
- If the patient is already on therapy with Vyvgart, have they shown clinical benefit? _____ *If yes, please provide documentation.*
- If the patient is already on therapy with Vyvgart, how many days have elapsed since the last treatment? _____
- If the patient is already on therapy with Vyvgart, is there evidence of unacceptable toxicity or disease progression? _____
- Please submit the patient's IgG levels.
- Please submit the patient's objective signs of neurologic weakness exams (such as QMG score). If patient is already on therapy with Vyvgart, please provide scores from before and after therapy.

Important Note: As of form preparation, although Vyvgart Hytrulo is FDA approved for CIDP, commercial insurance carriers have not yet provided parameters for coverage. Until that is available, please use your best judgment in providing clinical information for coverage authorization.

■ **Intravenous: Vyvgart (efgartigimod alfa-fcab) Medication Order**

☐ First treatment cycle, 10 mg/kg weekly for 4 weeks
☐ Second treatment cycle, 10 mg/kg weekly for 4 weeks (If ordered together with 1st cycle, _____ days after the prior treatment cycle ends.)

- *For patients 120kg or more, the recommended dose is 1,200mg per infusion. Please check here ☐ if you want to override this dosage.*
- *Note: 7 weeks was median in clinical trials. 2nd treatment cycle does not need to be selected before the 1st cycle is complete.*

Infusion administered through 0.2 micron filtered tubing. Dose administered in 125ml of normal saline over 1 hour. Prepare and administer per manufacturer instructions. Post infusion flush with normal saline. Monitor patient throughout infusion and for 1 hour afterward.

■ **Subcutaneous: Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase) Medication Order**

☐ First treatment cycle, 1,008mg efgartigimod alfa and 11,200 units hyaluronidase injected SQ, once weekly for 4 weeks.
☐ Second treatment cycle, 1,008mg efgartigimod alfa and 11,200 units hyaluronidase injected SQ, once weekly for 4 weeks.
(If ordered together with 1st cycle, _____ days after the prior treatment cycle ends.)

Injection administered subcutaneously over 30-90 seconds via winged infusion set. Prepare and administer per manufacturer instructions. Monitor patient throughout and for at least 30 minutes afterward.

■ **Rescue Management in Case of Reaction**

These include fever, chills, rigors, headache, rash, itching, swelling, edema, nausea, vomiting, abdominal pain, hypotension, and respiratory distress.

- Follow standing reaction orders, including diphenhydramine, methylprednisolone, albuterol and oxygen as needed.
- For severe reactions, administer Epi-pen or equivalent and call 911. Repeat if severe symptoms persist.
- Call ordering provider to report reaction.

■ **Ordering Provider Authorization**

Provider Signature: _____ Name: _____ Date: _____

Address: _____

Phone: _____ Fax: _____ Indiv. NPI #: _____ License: _____

Best Contact Person in Office: _____ Direct Phone to Contact Person: _____

FAX THIS ORDER AND SUPPORTING DOCUMENTATION TO 201-266-0437 OR UPLOAD USING YOUR SECURE DEDICATED WEBPAGE – TO GET A PERSONAL LINK PLEASE CONTACT THE INTAKE TEAM.

MG Activities of Daily Living (MG-ADL) Profile

argenx

GRADE 0=normal, 3=most severe	**0**	**1**	**2**	**3**	**Score** **(0, 1, 2, or 3)**
1. Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal, but can be understood	Difficult to understand speech	
2. Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	
3. Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	
4. Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	
5. Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	
6. Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	
7. Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	
8. Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	
				Total score (items 1-8) = Max 24 points	

Source: Wolfe GI et al. *Neurology*. 1999;52(7):1487-1489. doi:10.1212/wnl.52.7.1487