UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1492-1
Program	Prior Authorization/Notification
Medication	*Vyvgart Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc) *This program applies to the prefilled syringe formulation for self-administered subcutaneous use
P&T Approval Date	9/2025
Effective Date	12/1/2025

1. Background:

Vyvgart Hytrulo is a combination of efgartigimod alfa, a neonatal Fc receptor (FcRn) blocker, and hyaluronidase, an endoglycosidase, indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive and chronic inflammatory demyelinating polyneuropathy (CIDP).

2. Coverage Criteria[a]:

A. Generalized Myasthenia Gravis

1. **Initial Authorization**

a. **Vyvgart Hytrulo** will be approved based on **all** of the following criteria:

(1) Diagnosis of generalized Myasthenia Gravis (gMG)

-AND-

(2) Positive serologic test for anti-AChR antibodies

-AND-

(3) Patient is **not** receiving Vyvgart Hytrulo in combination with **any** of the following for treatment of the same indication:

(a) A complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]
(b) Another FcRn blocker [e.g., Imaavy (nipocalimab), Rystiggo (rozanolixizumab)]
(c) Immune globulin (e.g., Gammagard, Privigen, Hizentra)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Vyvgart Hytrulo** will be approved based on **both** of the following criteria:

(1) Documentation of a positive clinical response to Vyvgart Hytrulo

-AND-

(2) Patient is **not** receiving Vyvgart Hytrulo in combination with **any** of the following for treatment of the same indication:

(a) A complement inhibitor [e.g., eculizumab, Ultomiris (ravulizumab), Zilbrysq (zilucoplan)]
(b) Another FcRn blocker [e.g., Imaavy (nipocalimab), Rystiggo (rozanolixizumab)]
(c) Immune globulin (e.g., Gammagard, Privigen, Hizentra)

Authorization will be issued for 12 months.

B. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

1. **Initial Authorization**

a. **Vyvgart Hytrulo** will be approved based on **both** of the following criteria:

(1) Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP)

-AND-

(2) Patient is not receiving Vyvgart Hytrulo in combination with an immune globulin (e.g., Gammagard, Privigen, Hizentra) for treatment of the same indication

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Vyvgart Hytrulo** will be approved based on **both** of the following criteria:

(1) Documentation of a positive clinical response to Vyvgart Hytrulo

-AND-

(2) Patient is not receiving Vyvgart Hytrulo in combination with an immune globulin (e.g., Gammagard, Privigen, Hizentra) for treatment of the same indication

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Medical Necessity may be in place.

4. References:

1. Vyvgart Hytrulo® [prescribing information]. Boston, MA: Argenx US, Inc.; April 2025

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Change Control	
9/2025	New program.