SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) **(J9334) (Medical)**
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

- **Quantity Limit** (max daily dose) [NDC Unit]:
  - Vyvgart Hytrulo 1,008 mg/11,200 units (efgartigimod alfa/hyaluronidase) single-dose vial: 1 vial per week
  - Vyvgart Hytrulo 1,000 mg/10,000 units (efgartigimod alfa/hyaluronidase) single-dose prefilled syringe: 1 syringe per week
- **Max Units** (per dose and over time) [HCPCS Unit]:
  - 1,008 mg/11,200 units: 504 billable units per vial per week
  - 1,000 mg/10,000 units: 500 billable units per syringe per week

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Length of Authorization: Initial coverage will be provided for 6 months and may be renewed annually thereafter

- ❑ Member is 18 years of age or older
- ❑ Prescribed by or in consultation with a specialist for CIDP
- ❑ Member has progressive or relapsing and remitting CIDP for > 2 months **(submit documentation)**
- ❑ Member was determined to have Probable or Definite CIDP according to EFNS/PNS 2010
- ❑ Member has decreased or absent deep tendon reflexes in upper or lower limbs
- ❑ Electrodiagnostic testing indicating demyelination must meet **TWO** of the following:
  - ❑ Partial motor conduction block in at least 2 motor nerves or in 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve
  - ❑ Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve
  - ❑ Abnormal temporal dispersion conduction must be present in at least 2 motor nerves
  - ❑ Reduced motor conduction velocity in at least 2 motor nerves
  - ❑ Prolonged distal motor latency in at least 2 motor nerves
  - ❑ Absent F wave in at least 2 motor nerves plus one other demyelination criterion listed here in at least 1 other nerve
  - ❑ Prolonged F wave latency in at least 2 motor nerves
  - ❑ ≥30% amplitude reduction of the proximal negative peak CMAP relative to distal, excluding the posterior tibial nerve, if distal negative peak CMAP≥20% of LLN, in two nerves, or in one nerve + ≥1 other demyelinating parameter in ≥1 other nerve
- ❑ Member has a baseline CIDP Disease Activity Status (CDAS) score ≥ 2 **(submit documentation)**
- ❑ Members baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., INCAT, Medical Research Council (MRC) muscle strength **(submit documentation)**
- ❑ Member has tried and failed at least a 3-month trial of immunoglobulin (IG) or plasma exchange therapy **(submit documentation to support inadequate efficacy)**
- ❑ Requested medication will **NOT** be used as maintenance therapy in combination with immunoglobulin or intravenous efgartigimod

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Medication being provided by (check applicable box(es) below):

- ❑ **Physician's office** **OR** ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: **9/26/2024**
REVISED/UPDATED/REFORMATTED: ~~10/15/2024; 7/9/2025;~~ **8/15/2025**