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: (select one drug below)

❑ **Vyvgart®** (efgartigimod alfa-fcab) **IV (J9332)**	❑ **Vyvgart® Hytrulo** (efgartigimod alfa/hyaluronidase-qvfc) **SC (J9334)**

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 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.

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Recommended Dosage:

Drug	Dosing and Quantity Limit
Vyvgart (efgartigimod alfa-fcab) 400 mg/20 mL single-dose vial	• The recommended dosage is 10 mg/kg administered as an intravenous infusion over one hour once weekly for 4 weeks. In patients weighing 120 kg or more, the recommended dose is 1200 mg per infusion. • **Quantity limit: 3 vials per week for four doses per 50 days; 200 billable units per vial = 600 billable units per week** • **Maximum Dose (over time) – 1200 mg weekly for four doses per 50 days or every 8-week cycle**
Vyvgart Hytrulo (efgartigiomod alfa/ hyaluronidase-qvfc) 1,008 mg/11,200 units per 5.6 mL single-dose vial	• The recommended dosage is 1,008 mg/11,200 units administered subcutaneously over approximately 30 to 90 seconds in cycles of once weekly injections for 4 weeks. • **Quantity limit: 1 vial per week for four doses per 50 days = 504 billable units per vial per week** • **Maximum Dose (over time) – 1,008 mg/11,200 units weekly for four doses per 50 days or every 8-week cycle**
Vyvgart Hytrulo (efgartigiomod alfa/ hyaluronidase-qvfc) 1,000 mg/10,000 units per 5 mL single-dose prefilled syringe	• The recommended dosage is 1,000 mg/10,000 units administered subcutaneously over approximately 20 to 30 seconds in cycles of once weekly injections for 4 weeks. • **Quantity limit: 1 syringe per week for four doses per 50 days = 500 billable units per syringe per week** • **Maximum Dose (over time) – 1,000 mg/10,000 units weekly for four doses per 50 days or every 8-week cycle**

- Administer subsequent treatment cycles based on clinical evaluation; the safety of initiating subsequent cycles sooner than 50 days from the start of previous treatment cycle has not been established.

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.

Initial Authorization: 6 months

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- ❑ Prescribing physician must be a neurologist
- ❑ Member must be 18 years of age or older
- ❑ Member must have Myasthenia gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease and have a positive serologic test for anti-acetylcholine receptor (AchR) antibodies (lab test must be submitted)
- ❑ 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) **(chart notes must be submitted**)
- ❑ Member has a baseline MG-Activities of Daily Living (MG-ADL) total score ≥ 5 **(results must be submitted)**
- ❑ Member has a baseline immunoglobulin G (IgG) level of at least 6 g/L (600 mg) **(results must be submitted)**
- ❑ Member has **ONE** of the following **(verified by chart notes or pharmacy paid claims)**:
  - ❑ Member has tried and had an inadequate response to pyridostigmine
  - ❑ Member has an intolerance, hypersensitivity or contraindication to pyridostigmine
- ❑ Member has **ONE** of the following **(verified by chart notes or pharmacy paid claims)**:
  - ❑ Member failed over 1 year of therapy with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate)
  - ❑ Member failed at least 1 immunosuppressive therapy and required chronic plasmapheresis, plasma exchange (PE) or intravenous immunoglobulin (IVIG)
- ❑ Member will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., aminoglycosides, fluoroquinolones, beta-blockers, botulinum toxins, hydroxychloroquine)
- ❑ Member does **NOT** have an active infection, including clinically important localized infections
- ❑ Requested medication will **NOT** be administered with live-attenuated or live vaccines during treatment
- ❑ Medication will **NOT** be used in combination with other immunomodulatory biologic therapies (e.g., rituximab, eculizumab, ravulizumab, rozanolixizumab-noli, zilucoplan)

Reauthorization: 6 months. 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.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has **NOT** experienced unacceptable toxicity from the drug (e.g., infections, severe hypersensitivity reactions infusion reactions)

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- ❑ Member meets **ONE** of the following:
  - ❑ Member has demonstrated an improvement of at least 2 points in the MG-ADL total score from baseline sustained for at least 4 weeks (**results must be submitted to document improvement**)
  - ❑ Member has demonstrated an improvement of at least 3 points from baseline in the Quantitative Myasthenia Gravis (QMG) total score sustained for at least 4 weeks **(results must be submitted to document improvement)**
- ❑ Member requires continuous treatment, after initial beneficial response, due to new or worsening disease activity **(Note: a minimum of 50 days must have elapsed from the start of the previous treatment cycle)**

EXCLUSIONS – Therapy will NOT be approved if member has history of any of the following:

- MGFA Class I or MG crisis at initiation of treatment (MGFA Class V)
- Use of rituximab within 6 months prior to treatment
- Use of IVIG or PE within 4 weeks prior to treatment
- Any active or clinically significant infections that has not been treated

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  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.*