

# AvMed

## PHARMACY 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 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

**Drug Requested:** Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc)  
Generalized Myasthenia Gravis (gMG)

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

Member Name: \_\_\_\_\_

Member AvMed #: \_\_\_\_\_ 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: \_\_\_\_\_

**Recommended Dosing:** SUBQ: 1,000 mg efgartigimod alfa/10,000 units hyaluronidase once weekly for 4 weeks. Subsequent treatment cycles of 1,000 mg efgartigimod alfa/10,000 units hyaluronidase once weekly for 4 weeks may be administered based on clinical evaluation.

**Quantity Limit:** 4 syringes per 28 days

**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**

- Prescribing physician must be a neurologist
- Member must be 18 years of age or older

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- 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  $\geq 5$  (**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, nipocalimab-aahu, inebilizumab-cdon)

**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)
- 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**)

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- ❑ Member requires continuous treatment, after initial beneficial response, due to new or worsening disease activity. Subsequent treatment cycles should be administered based on clinical evaluation.

**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 Specialty Pharmacy – Proprium Rx**

***\*\*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.\****