AvMed

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 1-877-535-1391**. 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)
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

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- ❑ 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 **(submit documentation)**
- ❑ 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, 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.*

***Approved by Pharmacy and Therapeutics Committee:** ~~5/22/2025; 7/24/2025; 11/20/2025;~~**7/23/2026**
REVISED/UPDATED/REFORMATTED: ~~6/11/2025; 8/18/2025, 12/8/2025; 2/18/2026;~~ **8/28/2026**