Kaiser Permanente Health Plan of Mid-Atlantic States, Inc.
Vyvgart Hytrulo (efgartigimod and hyaluronidase) Prior Authorization (PA)
Pharmacy Benefits Prior Authorization Help Desk
Length of Authorizations: Initial- 6 months;
Continuation- 6 months (myasthenia gravis), 12 months (CIDP)

Instructions:

This form is used by Kaiser Permanente and/or participating providers for coverage of **Vyvgart Hytrulo (efgartigimod and hyaluronidase)** for **Commercial, Exchange, FEHB (Federal), MD Medicaid,** and **VA Medicaid** plans. Please complete all sections, incomplete forms will delay processing. Fax this form back to Kaiser Permanente within 24 hours fax: 1-866-331-2104. If you have any questions or concerns, please call 1-866-331-2103. **Requests will not be considered unless this form is complete. The KP-MAS Formulary can be found at:** Pharmacy | Community Provider Portal | Kaiser

1 – Patient Information

Patient Name: _____ Kaiser Medical ID#: _____ Date of Birth: _____

2 – Provider Information

Provider Name: _____ Specialty: _____ NPI: _____

Provider Address: _____

Provider Phone #: _____Provider Fax #: _____

Do you have an approved provider referral number from Kaiser Permanente?
□ Yes – please provide your provider referral number here: _____

3 – Pharmacy Information

Pharmacy Name: _____ Pharmacy NPI: _____

Pharmacy Phone #_____ Pharmacy Fax #: _____

4 – Drug Therapy Requested

Drug 1: Name/Strength/Formulation: _____
Sig: _____
Drug 2: Name/Strength/Formulation: _____
Sig: _____

5– Diagnosis/Clinical Criteria

1. Is this request for initial or continuing therapy?
   □ Initial therapy □ Continuing therapy, start date: _____

2. Indicate the patient's diagnosis for the requested medication: _____

Clinical Criteria:

<u>If using for Myasthenia Gravis:</u>

1. Is the prescriber a Neurologist?
   □ No □ Yes

2. Is the patient ≥18 years of age?
   □ No □ Yes

3. Does the patient have a diagnosis of generalized myasthenia gravis (gMG)?
   □ No □ Yes

4. Is there a confirmed positive serological test for anti-acetylcholine receptor (AChR) antibodies?
   □ No □ Yes

5. Does the patient meet ONE of the following criteria?
   - No history of thymoma or thymic neoplasm
   - History of thymoma and has had a thymectomy that was completed over 3 months ago

   □ No □ Yes

6. Is the patient's Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥5?
   □ No □ Yes

7. Is the patient currently taking, or has severe intolerance or contraindication to, pyridostigmine for symptomatic management?
   □ No □ Yes

8. Has the patient tried a corticosteroid at maximum tolerated dose for at least 6 months, or has a contraindication to corticosteroid therapy?
   □ No □ Yes

9. Has the patient tried and failed, or has contraindication to chronic IV immunoglobulin (IVIG)?
   □ No □ Yes

If patient is using for CHRONIC therapy (Myasthenia Gravis):

10. Has the patient had a trial of at least **TWO oral non-steroidal immunosuppressive therapies** for the duration indicated, unless intolerant/contraindicated?
    - <u>First line:</u>
      - Azathioprine for at least 12 months

      □ No □ Yes

      - Mycophenolate for at least 12 months

      □ No □ Yes

    - <u>Alternative agents:</u>
      - Cyclosporine for at least 6 months

      □ No □ Yes

      - Tacrolimus for at least 12 months

      □ No □ Yes

11. Has the patient had a trial of preferred biologics (e.g., KP-preferred rituximab biosimilar* for at least 6 months)?
    □ No □ Yes

12. Has the patient had trial and failure of ALL of the following?
    - o Vyvgart
    - o Ultomiris
    - o Epysqli

    □ No □ Yes

If patient is using for BRIDGE therapy (Myasthenia Gravis):

13. Does the patient have documented non-responsiveness to ALL of the following as bridge therapy *[Note: Vyvgart may be used for 12-24 months when used as a bridge to slower-acting immunotherapies (e.g., azathioprine, mycophenolate) if desirable to avoid steroid or minimize glucocorticoid use (e.g., poorly controlled diabetic patients)]*?
    - o IVIG
    - o Vyvgart
    - o Ultomiris
    - o Epysqli

    □ No □ Yes

14. Is the patient also being started on a non-steroidal immunosuppressive therapy (e.g., azathioprine, mycophenolate, rituximab, cyclophosphamide, cyclosporine, tacrolimus, methotrexate)?
    □ No □ Yes

<u>If using for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP):</u>

1. Is the request for efgartigimod and hyaluronidase (Vyvgart Hytrulo)?
   □ No □ Yes

2. Is the prescriber a Neurologist?
   □ No □ Yes

3. Is the patient ≥18 years of age?
   □ No □ Yes

4. Does the patient have a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP)?
   □ No □ Yes

5. Has the patient had an inadequate response to corticosteroids for at least 3 months?
   □ No □ Yes

6. Has the patient had an inadequate response, intolerance, or contraindication to immune globulin (IVIG) for at least 3 months?
   □ No □ Yes

7. Is the patient dependent on chronic IVIG or chronic oral prednisone equivalent (if no contraindication), AND has tried and failed at least ONE of the following for ≥6 months?
    - o KP-preferred rituximab biosimilar*
    - o Azathioprine
    - o Mycophenolate

    □ No □ Yes

**Notes:*

- *Riabni is the KP-preferred rituximab biosimilar*

- *Vyvgart Hytrulo comes in two dosage forms:*
  - *A syringe, which can be self-administered by patients and/or caregivers, and*
  - *A single dose vial, which is administered a winged infusion set as a subcutaneous injection over 30 to 90 seconds by a healthcare professional*
- *These criteria apply to the **syringe** (self/caregiver-administered) dosage form*
- *Vyvgart Hytrulo (efgartigimod and hyaluronidase) has an additional indication for CIDP, whereas Vyvgart (efgartigimod) does NOT have the CIDP indication*

For continuation of therapy, please respond to <u>additional questions</u> below. New members who were initiated on therapy outside of Kaiser, who have not been reviewed previously, must meet all above Clinical Criteria.

<u>If using for Myasthenia Gravis:</u>

1. If <u>first renewal</u>: Is there documented improvement of at least 2 point on the MG-ADL?
   □ No □ Yes

2. For <u>subsequent renewals after the first renewal</u>:
   - If using for **CHRONIC** therapy: Is there documented maintenance of stable MG-ADL score OR documented beneficial effect from therapy during Neurology follow-up in the last 12 months?
     □ No □ Yes

   - If using for **BRIDGE** therapy: Does provider confirm that the medication can be discontinued after 12 months of therapy? *(Note: it takes 12-24 months for slower acting immunotherapies (e.g., azathioprine, mycophenolate) to take effect)*
     □ No □ Yes

<u>If using for CIDP:</u>

1. Has the patient experienced a positive clinical response to treatment, as documented by Neurologist?
   □ No □ Yes

2. Has the patient had follow-up appointment with a Neurologist in the last 12 months?
   □ No □ Yes

6 – Provider Sign-Off

Additional Information –

1. **Please submit chart notes/medical records for the patient that are applicable to this request.**
2. **If member has not tried preferred agent(s) please provide rationale/explanation and any additional supporting information that should be taken into consideration for the requested medication:**

_____

_____

_____

I certify that the information provided is accurate. Supporting documentation is available for State audits.

Provider Signature:	**Date:**

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