# Clinical Oversight Review Board (CORB) Criteria for Prescribing/ Criteria-Based Consultation (CBC) Criteria for Coverage

# Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)

**Notes**:
- Quantity Limits: Yes

Non-Formulary **efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

**Initiation (new start) criteria, criteria for *current Kaiser Permanente members* already taking the medication who have not been reviewed previously:** Non-formulary **efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)** will be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

1. **Diagnosis of Myasthenia Gravis**
   - Prescribed by a neurologist with specialty in neuromuscular disorders
   - Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies
   - Patient has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of 5 or more
   - Prior inadequate response to at least two of the following:
     i. Corticosteroid (at least 50 mg prednisone equivalent daily) for at least 3 months
     ii. Azathioprine (at least 2 mg/kg daily) for at least 9-12 months
     iii. Rituximab for at least 8 months (ie at least 2 infusion cycles)
     iv. Other disease modifying therapy (e.g., cyclophosphamide, mycophenolate mofetil, cyclosporine, methotrexate), for at least 6-9 months
   - Patient is dependent on chronic intravenous immunoglobulin (IVIG) or chronic plasma exchange (PLEX).

2. **Diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy**
   - Prescribed by a neurologist with specialty in neuromuscular disorders
   - Patient meets one of the following categories:
     a) Prior inadequate response to at least <u>two</u> of the following:
       - Corticosteroid (at least 60 mg prednisone equivalent daily) for at least 3 months
       - IVIG (2 g/kg loading dose and at least 1 g/kg every 3 weeks) for at least 3 months
       - Chronic plasma exchange (PLEX) for at least 3 months

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b) Patient is dependent on chronic IVIG **AND** has tried and failed at least <u>one</u> of the following for 9 months or more:
- Azathioprine
- Mycophenolate
- Methotrexate

c) Patient is dependent on chronic plasma exchange (PLEX) **AND** has tried and failed at least <u>one</u> of the following for 9 months or more:
- Azathioprine
- Mycophenolate
- Methotrexate

d) Patient is dependent on chronic oral prednisone (doses greater than 10 mg/day) **AND** has tried and failed at least <u>one</u> of the following for 9 months or more:
- Azathioprine
- Mycophenolate
- Methotrexate

**<u>Criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously:</u>** Non-formulary **efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)** will be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- Patient has a diagnosis of myasthenia gravis or chronic inflammatory demyelinating polyneuropathy
- Patient is stable on medication and has experienced a positive clinical response to treatment

**<u>Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication:</u>** Non-formulary **efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)** will continue to be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- Prescribed by a neurologist with specialty in neuromuscular disorders
- Patient has experienced a positive clinical response to treatment, as documented by neurologist.

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