

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 12 months 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 two 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 one 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 one 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 one of the following for 9 months or more:
 - Azathioprine
 - Mycophenolate
 - Methotrexate

Criteria for new members entering Kaiser Permanente 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 12 months 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

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