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

## Zilucoplan (Zilbrysq)

Notes:

• Quantity Limits: Yes

Non-Formulary **zilucoplan (Zilbrysq)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

## Initiation (new start) criteria, and criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-

formulary **zilucoplan (Zilbrysq)** will be covered on the prescription drug benefit for <u>12</u> <u>months</u> when the following criteria are met:

- Prescribed by neurologist with specialty in neuromuscular disorders
- Patient has a diagnosis of myasthenia gravis
- Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies
- Prescriber enrolled in Zilbrysq Risk Evaluation and Mitigation Strategy (REMS) program
- Patient is dependent on, or cannot tolerate, intravenous immunoglobulin (IVIG) or chronic plasma exchange (PLEX)
- Patient is dependent on corticosteroids at a dose of more than 10 mg prednisone equivalent per day for disease control, despite a concurrent trial of at least two of the following steroid sparing agents:
  - Azathioprine (at least 2 mg/kg daily) for at least 9 months
  - Mycophenolate mofetil for at least 6 months
  - o Methotrexate for at least 6 months
  - Rituximab for at least 8 months (ie at least 2 infusion cycles)
- Prior inadequate response, or was unable to tolerate to the following:
  - Efgartigimod (Vyvgart) [requires authorization] OR efgartigimod and hyaluronidase (Vyvgart Hytrulo) [requires authorization] AND
  - Ravulizumab (Ultomiris) [requires authorization] for at least 6 months (3 infusion cycles)

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

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Revised: 11/14/24 Effective: 01/19/25 All plans offered and underwritten by Kaiser Foundation Health Plan of the Northwest



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## Zilucoplan (Zilbrysq)

- Patient has a diagnosis of myasthenia gravis
- Patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies
- Prior inadequate response, or was unable to tolerate ravulizumab (Ultomiris) [requires authorization] for at least 6 months (3 infusion cycles)

<u>Continued use criteria for patients previously approved per the above criteria who</u> <u>are currently stable on the medication</u>: Non-formulary zilucoplan (Zilbrysq) will continue to be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

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

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