

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

## Pegcetacoplan (Empaveli)

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

**Initiation (new start) criteria:** Non-formulary **pegcetacoplan (Empaveli)** will be covered on the prescription drug benefit for 16 weeks when the following criteria are met:

### **For paroxysmal nocturnal hemoglobinuria (PNH)**

- Prescribed by Hematology/ Oncology provider enrolled in EMPAVELI REMS
- Patient is at least 18 years of age
- Documentation of vaccination against Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B at least 2 weeks prior to the treatment start
- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- Either of the following clinical conditions (1 or 2):
  - 1) Patient has known allergy or intolerance of preferred agents ravulizumab and/or eculizumab

**-OR-**

  - 2) Patient has lack of response to ravulizumab and/or eculizumab defined as hemoglobin < 10.5 and continued need for transfusions after 3 months of treatment.

**Initiation (new start) criteria:** Non-formulary **pegcetacoplan (Empaveli)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

### **For complement 3 glomerulopathy (C3G)**

- Prescribed by Nephrologist enrolled in the EMPAVELI REMS
- Patient is above or equal to 12 years of age; and
- Biopsy-confirmed primary C3G; and
- Reduced serum C3 level below 77 mg/dL; and
- Ruled out secondary causes of C3 deposits on biopsy and low serum complement level (e.g., active/subclinical infection, paraproteinemia, systemic autoimmune disorders; and UPCR greater than or equal to 1g/g or 24 hour proteinuria greater than or equal to 1 g/day; and

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- Received vaccinations against Streptococcus pneumonia, Neisseria meningitidis (types AC, C, W, Y, and B), and Haemophilus influenza (type B) at least two weeks prior to the treatment start; and
- Trialed mycophenolate mofetil (MMF) in combination with corticosteroids; and optimizing baseline therapies below:
  - Angiotensin-converting enzyme inhibitors (ACEi) or angiotensin II receptor blockers (ARB)
  - Sodium-glucose cotransporter 2 inhibitor (SGLT2i: i.e., empagliflozin)
  - Statin for renal protective measures
  - Blood pressure management target below 130/80 mm Hg

**Criteria for current OR new Kaiser Permanente members already taking the medication who have not been reviewed previously:** Non-formulary **pegcetacoplan (Empaveli)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

### **For paroxysmal nocturnal hemoglobinuria (PNH)**

- Prescribed by Hematology/ Oncology provider enrolled in EMPAVELI REMS
- Patient is at least 18 years of age
- Documentation of vaccination against Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B
- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- Patient has documented continued response to pegcetacoplan evident by transfusion avoidance and hemolysis stabilization (reduction in LDH levels or increase in hemoglobin levels compared to baseline).

### **For Complement 3 glomerulopathy (C3G)**

- Prescribed by Nephrologist enrolled in the EMPAVELI REMS
- Patient is above or equal to 12 years of age; and
- Biopsy-confirmed primary C3G; and
- Documentation of vaccinations against Streptococcus pneumonia, Neisseria meningitidis (types AC, C, W, Y, and B), and Haemophilus influenza (type B)