

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:

- 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.

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:

- 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).