

**EMPAVELI
(pegcetacoplan)**

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Paroxysmal nocturnal hemoglobinuria (PNH)

AND ALL of the following:

- a. Documented baseline value for hemoglobin (Hgb)
- b. Vaccination against encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B at least 2 weeks prior to initiation [unless Empaveli (pegcetacoplan) treatment cannot be delayed]
- c. Prescriber is enrolled in Empaveli REMS program
- d. **NO** dual therapy with another Prior Authorization (PA) medication for PNH (see Appendix 1)

Prior - Approval Limits

Quantity 30 vials every 90 days

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Paroxysmal nocturnal hemoglobinuria (PNH)

AND ALL of the following:

- a. Increase in hemoglobin (Hgb) from pretreatment baseline

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- b. Prescriber is enrolled in Empaveli REMS program
- c. Absence of unacceptable toxicity from the drug
- d. **NO** dual therapy with another Prior Authorization (PA) medication for PNH (see Appendix 1)

Prior - Approval *Renewal* Limits

Same as above

Appendix 1 - List of PA Medications for PNH

Generic Name	Brand Name
eculizumab	Soliris
iptacopan	Fabhalta
pegcetacoplan	Empaveli
ravulizumab-cwvz	Ultomiris