

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	September 21, 2021

EMPAVELI™ (pegcetacoplan)

LENGTH OF AUTHORIZATION: Up to one year

INITIAL REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient must have documentation indicating a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH).
 - Supporting documentation includes diagnosis codes in medical claims history, progress notes, and/or discharge notes.
- The prescribing physician must be a hematologist for PNH.
- Documented baseline values for one or more of the following (necessary for renewal): serum lactate dehydrogenase (LDH), hemoglobin level, and packed RBC transfusion requirement.
- Patient must have been vaccinated against encapsulated bacteria (*Streptococcus pneumoniae*, *Nisseria meningitidis*, and *Haemophilus influenzae* type B). If patient has not been previously vaccinated, then the patient must be vaccinated at least 2 weeks prior to first dose of Empaveli™ according to the Advisory Committee on Immunization Practices (ACIP) guidelines.
 - Verify vaccination via CPT codes in medical claims history, physician progress notes, or vaccination records.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of positive clinical response.
- Dosing is appropriate as per labeling or is supported by compendia

DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as 1,080 mg/20 mL (54 mg/mL) single-dose vial.