



Pharmacy Drug Policy & Procedure

Policy Name:	Empaveli (pegcetacoplan)	Policy#:	3101P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Empaveli (pegcetacoplan)

Statement of the Policy

Health Alliance Medical Plans will approve the use of Empaveli (pegcetacoplan) under the specialty pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)
- 1.2 Age 18 years or older
- 1.3 Prescribed by or with a hematologist (blood doctor), immunology specialist (immune system doctor), or oncologist (cancer doctor)
- 1.4 Documentation of meningococcal vaccine series OR will receive vaccine at least 2 weeks prior to first dose
- 1.5 Review of chart notes documenting diagnosis and confirming that the patient has met all of the above requirements for treatment with Empaveli by both a pharmacist and medical director

2. Approval Period

- 2.1 Initial: 12 months
- 2.2 Subsequent Approvals: 12 months documentation of positive clinical response to therapy (e.g., improvement in hemoglobin level, hemoglobin stabilization, decrease in the number of red blood cell transfusions)

CPT Codes

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HCPCS Codes

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References

- 1. Empaveli (pegcetacoplan) [prescribing information]. Waltham, MA: Apellis Pharmaceuticals; January 2024.
- 2. Wong RSM, Pullon HWH, Amine I, et al. Inhibition of C3 with pegcetacoplan results in normalization of hemolysis markers in paroxysmal nocturnal hemoglobinuria. *Ann Hematol.* 2022 Sep;101(9):1971-1986.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.