AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Empaveli (pegcetacoplan)	Page:	1 of 2
Effective Date:	8/4//2025	Last Review Date:	5/2025

Applies to:	☒Illinois	☐New Jersey	☐Maryland	☐KY PRMD
	☐Florida Kids	☐Pennsylvania Kids	☐Virginia	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Empaveli under the patient's prescription drug benefit.

Description:

FDA-Approved Indication
Empaveli is indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

All other indications are considered experimental/investigational and not medically necessary

Applicable Drug List:

Empaveli

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:
Initial requests: Flow cytometry used to show results of glycosylphosphatidylinositol anchored proteins (GPI-APs) deficiency.

Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Criteria for Initial Approval:
Paroxysmal Nocturnal Hemoglobinuria
Authorization of 6 months may be granted for treatment of paroxysmal nocturnal hemoglobinuria (PNH) when ALL the following criteria are met:

- The diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) (e.g., at least 5% PNH cells, at least 51% of GPI-AP deficient poly-morphonuclear cells).
- Flow cytometry is used to demonstrate GPI-APs deficiency.
- Member has and exhibits clinical manifestations of disease (e.g., LDH > 1.5 ULN, thrombosis, renal dysfunction, pulmonary hypertension, dysphagia).
- The requested medication will not be used in combination with another complement inhibitor (e.g., Fabhalta, Piasky, Soliris, Ultomiris) for the treatment of PNH [for Soliris (eculizumab) and Ultomiris (ravulizumab) transition to Empaveli is allowed].

Criteria for Continuation of Therapy:
Paroxysmal Nocturnal Hemoglobinuria

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when ALL the following criteria are met:

- There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
- The member demonstrates a positive response to therapy (e.g., improvement in hemoglobin levels, normalization of lactate dehydrogenase [LDH] levels).
- The requested medication will not be used in combination with another complement inhibitor (e.g., Fabhalta, Piasky, Soliris, Ultomiris) for the treatment of PNH

Approval Duration and Quantity Restrictions:

Initial Approval: 6 months
Renewal Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Empaveli [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; February 2024.
2. Parker CJ. Management of paroxysmal nocturnal hemoglobinuria in the era of complement inhibitory therapy. Hematology. 2011; 21-29.
3. Borowitz MJ, Craig F, DiGiuseppe JA, et al. Guidelines for the Diagnosis and Monitoring of Paroxysmal Nocturnal Hemoglobinuria and Related Disorders by Flow Cytometry. Cytometry B Clin Cytom. 2010: 78: 211-230.
4. Preis M, Lowrey CH. Laboratory tests for paroxysmal nocturnal hemoglobinuria (PNH). Am J Hematol. 2014;89(3):339-341.
5. Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. Hematology Am Soc Hematol Educ Program. 2016;2016(1):208-216.
6. Dezern AE, Borowitz MJ. ICCS/ESCCA consensus guidelines to detect GPI-deficient cells in paroxysmal nocturnal hemoglobinuria (PNH) and related disorders part 1 - clinical utility. Cytometry B Clin Cytom. 2018 Jan;94(1):16-22.