AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Empaveli (pegcetacoplan)	Page:	1 of 3
Effective Date:	2/9/2026	Last Review Date:	1/2026

Applies to:	☐Illinois	☐Florida	☐Florida Kids
	☒New Jersey	☐Maryland	☐Michigan
	☐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 Indications[1]

Empaveli is indicated for:

- Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH) – *Review under New Jersey State Protocol for Paroxysmal Nocturnal Hemoglobinuria Products*
- Treatment of adult and pediatric patients aged 12 years and older with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce proteinuria.

Applicable Drug List:

Empaveli

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

For initial requests:

- Complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN):
  - Kidney biopsy confirming a diagnosis of complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN).
  - Laboratory report and/or chart note(s) indicating the member has proteinuria greater than or equal to 1 g/day or baseline urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.0 g/g obtained within 3 months prior to initiation of the requested drug.

For continuation requests:

- Complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN): Laboratory report and/or

chart note(s) indicating the member has decreased levels of proteinuria or UPCR from baseline.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

- Complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN): nephrologist.

Coverage Criteria

Complement 3 Glomerulopathy (C3G) or Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN)[1]
Authorization of 12 months may be granted for treatment of complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) when all of the following criteria are met:

- Member has a diagnosis of complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) confirmed by kidney biopsy.
- Member has either of the following obtained within 3 months prior to initiation of the requested drug:
    - Proteinuria greater than or equal to 1 g/day.
    - UPCR greater than or equal to 1.0 g/g.
- Member has received a stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy (e.g., angiotensin converting enzyme inhibitor [ACEI] or angiotensin II receptor blocker [ARB]) and/or sodium-glucose cotransporter-2 (SGLT2) inhibitor therapy for at least 3 months prior to initiation of therapy, or member has an intolerance or contraindication to RAS inhibitors or SGLT2 inhibitor.

Continuation of Therapy

Complement 3 Glomerulopathy (C3G) or Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN)
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when all of the following criteria are met:

- There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
- The member is experiencing benefit from therapy as evidenced by either of the following:
  - Decreased levels of proteinuria from baseline.
  - Decrease in UPCR from baseline.

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.; July 2025.
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.