Mass General Brigham
Health Plan

Empaveli (pegcetacoplan)
Effective 04/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Empaveli (pegceacoplan) is a complement inhibitor indicated for the treatment of:

- Adults with paroxysmal nocturnal hemoglobinuria
- Adult and pediatric patients 12 years of age and older with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce proteinuria

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all of the following diagnosis-specific criteria are met:

Paroxysmal nocturnal hemoglobinuria (PNH)

1. The member has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry

C3 Glomerulopathy (C3G), Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN)

1. One of the following diagnoses:
    a. C3 glomerulopathy (C3G)
    b. Primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN)
2. For primary immune-complex membranoproliferative glomerulonephritis: member has not had a kidney transplant
3. Requested medication is being used to reduce proteinuria
4. Member is currently being treated with a maximally tolerated dose of one of the following for at least 12 weeks prior to initiating treatment:
    a. Angiotensin-converting enzyme inhibitor (e.g., benazepril, lisinopril)
    b. Angiotensin receptor blocker (e.g., losartan, valsartan)
    c. Sodium-glucose cotransporter-2 (SGLT2) inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin])
5. Requested medication is prescribed by or in consultation with a nephrologist

Continuation of Therapy

Reauthorization will be granted when all of the following diagnosis-specific criteria are met:

PNH

1. Prescriber submits documentation of a positive response to therapy (e.g., normalization of lactate dehydrogenase [LDH] levels, improvement in hemoglobin levels, decreased number of red blood cell transfusions)

C3G, IC-MGPN:

1. Prescriber submits documentation demonstrating member has had a positive clinical response to therapy (e.g., reduction in 24-hour UPCR, stable or improved eGFR compared to baseline)
2. For primary immune-complex membranoproliferative glomerulonephritis, member has not had a kidney transplant
3. Member continues to be treated with a maximally tolerated dose of one of the following:
    a. Angiotensin-converting enzyme inhibitor (e.g., benazepril, lisinopril)
    b. Angiotensin receptor blocker (e.g., losartan, valsartan)
    c. Sodium-glucose cotransporter-2 (SGLT2) inhibitor (e.g., Farxiga [dapagliflozin], Jardiance [empagliflozin])

Limitations

1. Initial and reauthorization approvals will be granted for 12 months
2. The following quantity limits apply on the pharmacy benefit:

Drug Name and Dosage Form	Quantity Limitation
Empaveli 1080mg/20mL	10 vials per 30 days

References

1. 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.
2. Empaveli (pegcetacoplan) injection [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; July 2025.
3. Parker CJ. Management of paroxysmal nocturnal hemoglobinuria in the era of complement inhibitory therapy. *Hematology.* 2011; 21-29.
4. Preis M, Lowrey CH. Laboratory tests for paroxysmal nocturnal hemoglobinuria (PNH). Am J Hematol. Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. Hematology Am Soc Hematol Educ Program. 2016;2016(1):208-216.

Review History

01/19/2022 – Created and Reviewed for Jan P&T. Effective 03/01/2022.
08/14/2024 – Reviewed and updated at August P&T. Updated criteria to require that the member has a diagnosis of PNH confirmed by flow cytometry. Updated reauthorization criteria to require documentation of a positive response to therapy. Initial and reauthorization requests approved for 12 months. Clarified step therapy language to indicate member must be new to the plan within the past 90 days. Effective 11/01/2024.
07/09/2025 – Reviewed at June P&T. No clinical changes. Effective 08/01/2025.
10/08/2025 – Reviewed and updated at October P&T. Updated policy to reflect that it no longer applies to the medical benefit. Effective 01/01/2026.

02/11/2026 – Reviewed and updated at November P&T. Updated policy to include the supplemental indication of C3 glomerulopathy (C3G) and IC-MGPN. Effective 04/01/2026.