Mass General Brigham
Health Plan

Complement Inhibitors
Empaveli (pegcetacoplan)
Effective 11/17/2025

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Notes	Empaveli is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Empaveli (pegceacoplan) is a complement inhibitor indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria.

Coverage Guidelines
Authorization may be reviewed for members new to the plan who are currently receiving treatment with Empaveli excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Complement 3 glomerulopathy (C3G)
1. Diagnosis of C3G
2. Member is ≥ 12 years of age
3. Prescriber is a nephrologist or consult notes from specialist are provided
4. ONE of the following:
    a. Inadequate response (defined as ≥ 90 days of therapy) to the maximum FDA-approved dose of an ACE inhibitor or ARB
    b. BOTH of the following:
        i. Inadequate response (defined as ≥ 90 days of therapy) to the maximally tolerated dose of an ACE inhibitor or ARB
        ii. Intolerance to an ACE inhibitor or ARB at a dose above the maximally tolerated dose
5. ONE of the following despite treatment with a maximally tolerated dose of an ACE inhibitor or ARB for ≥ 90 days:
    a. Urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g

    b. Proteinuria >1.0 g/day
6. Inadequate response, adverse reaction or contraindication to BOTH of the following:
    a. Mycophenolate
    b. Glucocorticoids
7. Appropriate dosing

Paroxysmal nocturnal hemoglobulinuria (PNH)

1. Diagnosis of PNH
2. The member is 18 years of age or older
3. Prescriber is a hematologist or consult notes from a specialist are provided
4. Inadequate response or adverse reaction to one or contraindication to all of the following: Piasky, Soliris, Ultomiris
5. Requested quantity is ≤ 8 injections (160 mL)/28 days

Primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN)

1. Diagnosis of IC-MPGN
2. Attestation member does not have IC-MPGN secondary to another condition (e.g., infection, malignancy, autoimmune disease)
3. Member is ≥ 12 years of age
4. Prescriber is a nephrologist or consult notes from specialist are provided
5. ONE of the following:
    a. Inadequate response (defined as ≥ 90 days of therapy) to the maximum FDA-approved dose of an ACE inhibitor or ARB
    b. BOTH of the following:
        i. Inadequate response (defined as ≥ 90 days of therapy) to the maximally tolerated dose of an ACE inhibitor or ARB
        ii. Intolerance to an ACE inhibitor or ARB at a dose above the maximally tolerated dose
6. ONE of the following despite treatment with a maximally tolerated dose of an ACE inhibitor or ARB for ≥ 90 days:
    a. Urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g
    b. Proteinuria >1.0 g/day
7. Inadequate response, adverse reaction to TWO or contraindication to ALL of the following:
    a. Cyclophosphamide
    b. Mycophenolate plus glucocorticoids
    c. Rituximab
8. Appropriate dosing

<u>Continuation of Therapy</u>

PNH

Reauthorization by physician will infer a positive response to therapy.

C3G or Primary IC-MPGN

Prescriber must provide documentation of positive clinical response (i.e., reduced proteinuria).

Limitations

1. Initial approvals will be granted based on indication
    a. C3G, Primary IC-MPGN: 6 months
    b. PNH: 12 months

2. Reauthorizations will be granted for 12 months.

References

1. Empaveli [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; Jan. 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. Kopel T, Salant DJ. C3 glomerulopathies: Dense deposit disease and C3 glomerulonephritis. In: Lam AQ (Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2025 Jun 11 [cited 2025 Jul 8]. Available from: http://www.utdol.com/online/index.do.
7. Fervenza FC, Sethi S. Membranoproliferative glomerulonephritis: Classification, clinical features, and diagnosis. In: Lam AQ (Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2024 Aug 12 [cited 2025 Jul 31]. Available from: http://www.utdol.com/online/index.do.
8. Moutsopoulos HM, Fragoulis GE, Stone JH. Treatment and prognosis of IgG4-related disease. In: Seo P (Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2025 Apr 15 [cited 2025 Jul 9]. Available from: http://www.utdol.com/online/index.do.
9. Moutsopoulos HM, Fragoulis GE, Stone JH. Clinical manifestations and diagnosis of IgG4-related disease. In: Seo P (Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2025 Mar 31 [cited 2025 Jul 9]. Available from: http://www.utdol.com/online/index.do.

Review History

01/19/2022 – Created and Reviewed for Jan P&T. Effective 03/01/2022
02/08/2023 - Reviewed and updated for Feb P&T. Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Updated reauth language. Initial approval durations updated to 12 months. Effective 4/1/23.
05/15/25 – Reviewed and updated for P&T. Performed annual medical criteria review. Policy has been updated to better reflect agents with prior authorization on medical benefit. Updated formatting and references. Criteria for Empaveli (pegcetacoplan) was updated to require step-through with Soliris (eculizumab) or Ultomiris (ravulizumab-cwvz) and include specified quantity limit. Criteria regarding meningococcal vaccination requirement for complement inhibitors was removed. Effective 6/1/25
10/8/25 – Reviewed and updated for P&T. Added new indications, C3G and primary IC-MPGN in pediatrics ≥12 years of age. Effective 11/17/25