Mass General Brigham
Health Plan

Complement Inhibitors
Empaveli (pegcetacoplan)
Effective 06/01/2025

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:

1. The member has a diagnosis of paroxysmal nocturnal hemoglobulinuria (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 ≤ 160 mL/30 days

Continuation of Therapy
Reauthorization by physician will infer a positive response to therapy.

Limitations

1. Initial approvals and 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.

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