Mass General Brigham
Health Plan

Empaveli® (pegcetacoplan)
Effective 04/01/2023

Plan	☒ MassHealth ☐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 when obtained through the pharmacy benefit.		
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
Exceptions	N/A		

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. The member has received a meningococcal vaccine at least two weeks prior to treatment initiation
4. Appropriate dosing

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
2. The following quantity limits apply:

Empaveli 1080mg/20mL	10 vials per 30 days

References

1. Empaveli [package insert]. Waltham, MA: Apellis Pharmaceuticals, Inc.; May 2021
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.