Empaveli® (pegcetacoplan)
Effective 03/01/2022

Plan	☐ MassHealth ☐ MH UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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 AllWays Health Partners 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. Diagnosis is confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) as demonstrated by either of the following:
    a. At least 5% PNH cells
    b. At least 51% of GPI-AP deficient poly-morphonuclear cells
3. Flow cytometry is used to demonstrate GPI-APs deficiency
4. Medical charts documenting baseline value for serum lactate dehydrogenase (LDH) is ≥ 1.5 times the upper limit of normal

Continuation of Therapy

Reauthorization will be granted if when provider when there is chart notes or medical record documentation stating no evidence of unacceptable toxicity or disease progression while on the current

regimen and demonstrate a positive response to therapy (e.g., improvement in hemoglobin levels, normalization of lactate dehydrogenase [LDH] levels).

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months
3. 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

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