Clinical Policy Title:	pegcetacoplan
Policy Number:	RxA.692
Drug(s) Applied:	Empaveli®
Original Policy Date:	08/16/2021
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Paroxysmal Nocturnal Hemoglobinuria (PNH) (must meet all):

1. Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH);
2. Diagnosis confirmed by flow cytometry;
3. Member has been vaccinated against encapsulated bacteria according to current ACIP guidelines at least 2 weeks prior to starting Empaveli®;
4. Member meets one of the following (a or b):
   a. Transfusion-dependent with hemoglobin ≤ 7 g/dL;
   b. Hemoglobin ≤ 9g/dL and experiencing symptoms of anemia;
5. Member has documented symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, organ damage);
6. If the member is switching from Soliris® (eculizumab) to Empaveli®, Soliris® should be continued for the first 4 weeks then discontinued;
7. If the member is switching from Ultomiris®, initiate Empaveli® no more than 4 weeks after the last dose of Ultomiris®.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Paroxysmal Nocturnal Hemoglobinuria (PHN) (must meet all):

1. Member is currently receiving or has been treated with this medication within the past 120 days, excluding manufacturer samples;
2. Member is responding positively to therapy as evidenced by decreased requirement of RBC transfusions, stabilization or improvement of hemoglobin, reduction of lactate dehydrogenase (LDH), stabilization or improvement of symptoms;
3. Member will not be using the requested agent in combination with Soliris® or Ultomiris®.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Parker C, Omine M, Richards S, et al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood. 2005;106(12):3699-3709. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1895106/. Accessed August 28, 2024.

2. Sahin F, Akay OM, Ayer M, et al. Pesg PNH diagnosis, follow-up, and treatment guidelines. Am J Blood Res. 2016;6(2):19-27. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4981648/. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/16/2021	09/14/2021
Policy was reviewed: 1. References were reviewed and updated.	04/20/2022	07/18/2022
Policy was reviewed: 1. References were reviewed and updated.	05/26/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with the new verbiage containing 120 days lookback period. 5. Updated approval duration verbiage. 6. References were reviewed and updated	08/28/2024	9/13/2024