

Clinical Policy Title:	pegcetacoplan
Policy Number:	RxA.692
Drug(s) Applied:	Empaveli®
Original Policy Date:	08/16/2021
Last Review Date:	12/11/2025
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 ≤ 9 g/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®.

B. Complement 3 Glomerulopathy (must meet all):

1. Diagnosis of complement 3 glomerulopathy;
2. Diagnosis confirmed by kidney biopsy;
3. Member meets one of the following (a or b):
 - a. UPCr ≥ 1 g/g;
 - b. Proteinuria > 1 g/day;
4. eGFR ≥ 30 mL/min/1.73 m² ;
5. Member has received a stable dose of an ACEI or ARB for at least 3 months prior to initiation of therapy, unless contraindicated or clinically significant adverse effects are experienced;
6. Trial and failure of an immunosuppressant and glucocorticoid for at least 6 months.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All indications (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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.
3. Empavelo. Package Insert. Apellis Pharmaceuticals, Inc.; 2021. Available at: https://pi.apellis.com/files/PI_Empaveli.pdf. Accessed August 1, 2025.

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
Policy was reviewed: 1. New indication of complement 3 glomerulopathy added to policy with criteria. 2. Continuation language updated.	8/1/2025	N/A
Policy reviewed.	12/11/2025	12/11/2025