Clinical Policy Title:	pegcetacoplan
Policy Number:	RxA.692
Drug(s) Applied:	Empaveli®
Original Policy Date:	08/16/2021
Last Review Date:	10/19/2023
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) confirmed by flow cytometry;
2. Age ≥ 18 years;
3. Prescribed by or in consultation with a hematologist, oncologist, or immunologist;
4. Member has been vaccinated against encapsulated bacteria according to current ACIP guidelines at least 2 weeks prior to starting Empaveli®;
5. Member is transfusion-dependent with hemoglobin ≤ 7 g/dL or ≤ 9g/dL and experiencing symptoms of anemia;
6. Member has documented symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, organ damage);
7. If the member is switching from Soliris®(eculizumab) to Empaveli®, Soliris®(eculizumab) should be continued for the first 4 weeks after starting the requested agent and then Soliris® (eculizumab) should be discontinued;
8. If the member is switching from Ultomiris®, initiate Empaveli® no more than 4 weeks after the last dose of Ultomiris®;
9. Dose does not exceed 2,160 mg per week or 1,080 mg every 3 days (total 10 doses per month) with documentation of a lactate dehydrogenase (LDH) level greater than 2 times the upper limit of normal (ULN).

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy as evidenced by decreased requirement of RBC transfusions, stabilization/improvement of hemoglobin, reduction of lactate dehydrogenase (LDH), stabilization/improvement of symptoms;
3. Member will not be using the requested agent in combination with Soliris® (eculizumab) or Ultomiris® (ravulizumab-cwvz);

4. If request is for a dose increase, new dose does not exceed 2,160 mg per week or 1,080 mg every 3 days (total 10 doses per month) with documentation of an LDH level greater than 2 times the ULN.

Approval Duration
Commercial: 12 months
Medicaid: 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 May 26, 2023.
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 May 26, 2023.

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