ALASKA MEDICAID
Prior Authorization Criteria

Empaveli™ (pegcetacoplan)

FDA INDICATIONS AND USAGE[1]

Empaveli™ is a complement inhibitor indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). Paroxysmal nocturnal hemoglobinuria is a rare acquired hematopoietic stem cell disorder in which red blood cells undergo cell lysis prematurely mediated by the alternative pathway of complement.

APPROVAL CRITERIA[1,2,3,4,5]

1. Patient's age is to FDA label **AND**;
2. Prescribed by or in consultation with a hematologist or oncologist **AND**;
3. Patient has diagnosis of PNH confirmed by flow cytometry diagnostic testing **AND;**
4. Patient has one of the following indications for therapy:
    a. Presence or history of a thrombotic event
    b. Presence of organ damage secondary to chronic hemolysis
    c. Patient has had at least 1 transfusion in 12 months
    d. Patient has high LDH activity (defined as ≥1.5 x ULN) with clinical symptoms **AND;**
5. Patient has documented baseline values for all the following:
    a. Serum lactate dehydrogenase (LDH)
    b. Documentation of hemoglobin < 10.5 g/dL;+
6. Patient has had the appropriate vaccinations against encapsulated bacteria at least 14 days prior to the first dose (I.E, Meningococcal vaccine)

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Patient is receiving Empaveli™ in combination with another complement inhibitor used for the treatment of PNH (I.E., Soliris®, Ultomiris®), unless the member is in a 4-week period of cross titration between Soliris® and Empaveli™
3. Patient has an unresolved serious infection caused by encapsulated bacteria
4. Prescriber is not enrolled in the REMS program.

CAUTIONS[1]

- The use of EMPAVELI may predispose individuals to serious, life-threatening, or fatal infections caused by encapsulated bacteria.
- Use of silica reagents in coagulation panels may result in artificially prolonged activated partial thromboplastin time (aPTT).

DURATION OF APPROVAL

- Initial Approval: 6 months
- Reauthorization 12 months with chart notes indicating the patient has had improvements or stabilization with the requested medication (I.E., decreased requirement of RBC transfusions, stabilization/improvement of hemoglobin, reduction of lactate dehydrogenase (LDH), stabilization/improvement of symptoms)

QUANTITY LIMIT[1]

- 10 vials per 30 days (1080mg administered every 3 days)
- HCPCS – J3490

REFERENCES / FOOTNOTES:

1. Empaveli [package insert], Waltham, MA: Apellis Pharmaceuticals, Inc.; May 2021.
2. Parker C, Omine M, Richards S, et al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood. 2005; 106(12):3699-3709.
3. Hillmen P, Szer J, Weitz IC, et al. Pegcetacoplan versus eculizumab in paroxysmal nocturnal hemoglobinuria. NEJM March 2021;384:1028-37.
4. Sutherland DR, Keeney M, Illingworth A. Practical guidelines for the high-sensitivity detection and monitoring of paroxysmal nocturnal hemoglobinuria clones by flow cytometry. Cytometry B Clin Cytom. 2012 Jul;82(4):195-208.
5. 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.