



Commercial/Healthcare Exchange PA Criteria Effective: September 14, 2021

Prior Authorization: Empaveli

Products Affected: Empaveli (pegcetacoplan) injection solution

Medication Description: Pegcetacoplan (Empaveli) is a complement inhibitor that binds to complement protein C3 and its activation fragment C3b, thus regulating the cleavage of C3 and the generation of downstream effectors of complement activation.

Covered Uses: Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

Exclusion Criteria:

1. Patients with hypersensitivity to pegcetacoplan or to any of the excipients.
2. Patients who are not currently vaccinated against certain encapsulated bacteria, unless the risks of delaying EMPAVELI treatment outweigh the risks of developing a bacterial infection with an encapsulated organism.
3. Patients with unresolved serious infection caused by encapsulated bacteria including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae*.

Required Medical Information:

1. Diagnosis
2. Medical chart notes

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with a hematologist

Coverage Duration: Initial: 4 months; Continuation: 1 year

Other Criteria:

I. Initial Approval Criteria

1. **Paroxysmal Nocturnal Hemoglobinuria (PNH):** Approve Empaveli if the patient meets the following criteria:

- A. Patient has a diagnosis of PNH; AND
- B. Empaveli is being used to treat member's hemolytic anemia due to PNH; AND
- C. For a patient transitioning to Empaveli from Soliris (eculizumab intravenous infusion) or Ultomiris (ravulizumab intravenous infusion), the prescriber attests that these such medications will be discontinued within 4 weeks after starting Empaveli.

II. Continued Therapy

- A. Patient is responding positively to therapy, as determined by the prescriber; AND
- B. Patient has not experienced unacceptable toxicity from the drug.

Last Res. September 2021



Confidential Information

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References:

1. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.
2. Empaveli PI prescribing information. Apellis Pharmaceuticals, Inc. Waltham, MA 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	9/14/2021

Last Res. September 2021



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