UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1361-4
Program	Prior Authorization/Notification
Medication	Empaveli® (pegcetacoplan)
P&T Approval Date	7/2021, 7/2022, 8/2023, 2/2024
Effective Date	5/1/2024

1. Background:

Empaveli (pegcetacoplan) is a complement inhibitor indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).[1]

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Empaveli** will be approved based on **all** of the following criteria:

   a. Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

   -AND-

   b. **Both** of the following:

      (1) Patient will not be prescribed Empaveli in combination with another complement inhibitor used for the treatment of PNH (e.g., Fabhalta, Soliris, Ultomiris)

      -AND-

      (2) **One** of the following:

         (a) Patient is not currently receiving a complement inhibitor medication used for the treatment of PNH (e.g., Fabhalta, Soliris, Ultomiris)

         -OR-

         (b) Patient is currently receiving Soliris (eculizumab) which will be discontinued after an initial 4 week overlap period with Empaveli

         -OR-

         (c) Patient is currently receiving Ultomiris (ravulizumab-cwvz) which will be stopped and Empaveli will be initiated no more than 4 weeks after the last dose

Authorization will be issued for 12 months.

B. Reauthorization

1. **Empaveli** will be approved based on **all** of the following criteria:

   a. Documentation of positive clinical response to Empaveli therapy

   -AND-

   b. Patient is not receiving Empaveli in combination with another complement inhibitor used for the treatment of PNH (e.g., Fabhalta, Soliris, Ultomiris)

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may also be in place.

4. References:

1. Empaveli [package insert], Waltham, MA: Apellis Pharmaceuticals, Inc.; September 2023.

Program	Prior Authorization/Notification - Empaveli® (pegcetacoplan)
Change Control	
7/2021	New program
7/2022	Annual review. Added state mandate with no other changes to coverage criteria.
8/2023	Annual review. Updated reference.
2/2024	Added Fabhalta to list of examples of other complement inhibitors used for the treatment of PNH. Revised initial authorization to 12 months. Included criteria for therapeutic duplication. Updated references.