

## Pegcetacoplan (Empaveli™)

### Goal(s):

- Restrict use to OHP-funded conditions and according to OHP guidelines for use.
- Promote use that is consistent with national clinical practice guidelines and medical evidence.
- Pegcetacoplan is approved by the FDA for the following indication:
  - Treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH)

### Length of Authorization:

Up to 12 months

### Requires PA:

- Empaveli™ (pegcetacoplan) pharmacy and physician administered claims

### Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at [www.orpdl.org](http://www.orpdl.org)
- Searchable site for Oregon FFS Drug Class listed at [www.orpdl.org/drugs/](http://www.orpdl.org/drugs/)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the diagnosis funded by OHP?	<b>Yes:</b> Go to #3	<b>No:</b> Pass to RPh. Deny; medical appropriateness
3. Is this request for continuation of therapy?	<b>Yes:</b> Go to <b>Renewal Criteria</b>	<b>No:</b> Go to # 4
4. Has the patient been vaccinated against <i>Streptococcus pneumoniae</i> , <i>Haemophilus influenzae</i> type B, and <i>Neisseria meningitidis</i> serogroups A, C, W, and Y and serogroup B according to current Advisory Committee on Immunization Practice (ACIP) recommendations for vaccination in patients with complement deficiencies?  Note: Prescribing information recommends vaccination at least 2 weeks prior to starting therapy. If the risk of delaying therapy outweighs the risk of developing a serious infection, a 2 week course of antibiotic prophylaxis must be immediately initiated if vaccines are administered less than 2 weeks before starting complement therapy.	<b>Yes:</b> Go to #5	<b>No:</b> Pass to RPh. Deny; medical appropriateness

## Approval Criteria

5. Is the diagnosis for an adult (age 18 years or older) with Paroxysmal Nocturnal Hemoglobinuria (PNH)?

**Yes:** Approve for 12 months

**No:** Pass to RPh. Deny; medical appropriateness

## Renewal Criteria

1. Is there objective documentation of treatment benefit from baseline?

Appropriate measures will vary by indication (e.g., hemoglobin stabilization, decreased transfusions, symptom improvement, functional improvement, etc.).

**Yes:** Approve for 12 months

Document baseline assessment and physician attestation received.

**No:** Pass to RPh. Deny; medical appropriateness

*P&T/DUR Review: 12/21 (DM)*

*Implementation: 1/1/22*