

**Request for Prior Authorization  
Pegcetacoplan (Empaveli)**

**FAX Completed Form To**  
1 (877) 733-3195  
**Provider Help Desk**  
1 (844) 236-1464

(PLEASE PRINT – ACCURACY IS IMPORTANT)

IA Medicaid Member ID #  _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Patient name	DOB
Patient address		
Provider NPI  _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Prescriber name	Phone
Prescriber address		Fax
Pharmacy name	Address	Phone
<b>Prescriber must complete all information above. It must be legible, correct, and complete or form will be returned.</b>		
Pharmacy NPI  _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _	Pharmacy fax	NDC  _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

**Prior authorization (PA) is required for pegcetacoplan (Empaveli). Payment will be considered under the following conditions:**

- 1) Request adheres to all FDA approved labeling including age, dosing, contraindications, warnings and precautions; and
- 2) Patient has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); and
- 3) Flow cytometry shows detectable glycosylphosphatidylinositol (GPI)-deficient hematopoietic clones or  $\geq 10\%$  PNH cells; and
- 4) History of at least one red blood cell transfusion in the previous 12 months; and
- 5) Documentation of hemoglobin  $< 10.5$  g/dL; and
- 6) Is not prescribed concurrently with eculizumab (Soliris) or ravulizumab (Ultomiris), unless the patient is in a 4 week period cross-titration between eculizumab (Soliris) and pegcetacoplan (Empaveli); and
- 7) Is prescribed by or in consultation with a hematologist; and
- 8) Medication will be administered in the member's home; and
- 9) Member or member's care giver has been properly trained in subcutaneous infusion and prescriber has determined home administration is appropriate.

Initial authorizations will be approved for 4 weeks if within cross-titration period with eculizumab (Soliris) to verify eculizumab has been discontinued, or for 6 months otherwise.

Additional authorizations will be considered when the following criteria are met:

- 1) Documentation of a positive clinical response to therapy (e.g., increased or stabilization of hemoglobin levels or reduction in transfusions); and
- 2) Is not prescribed concurrently with eculizumab (Soliris) or ravulizumab (Ultomiris).

Non-Preferred

Empaveli

<b>Strength</b>	<b>Dosage Instructions</b>	<b>Quantity</b>	<b>Days Supply</b>
_____	_____	_____	_____

**Diagnosis:** \_\_\_\_\_

**Request for Prior Authorization-Continued  
Pegcetacoplan (Empaveli)**

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Flow cytometry shows detectable GPI-deficient hematopoietic clones or ≥ 10% PNH cells?  Yes  No

Does patient have a history of at least one red blood cell transfusion in the previous 12 months?

Yes Date: \_\_\_\_\_  No

Document hemoglobin: \_\_\_\_\_ Date obtained: \_\_\_\_\_

Is pegcetacoplan being prescribed concurrently with eculizumab or ravulizumab?

Yes (provide rationale): \_\_\_\_\_  
 No

Prescriber Specialty:  Hematologist  
 Other (specify): \_\_\_\_\_

If other, note consultation with hematologist: Consultation date: \_\_\_\_\_

Physician name, specialty & phone: \_\_\_\_\_

Place of administration:  Member's home  Other: \_\_\_\_\_

Has member or member's care giver been properly trained in subcutaneous infusion and prescriber has determined home administration is appropriate?  Yes  No

**Renewal Requests**

Is pegcetacoplan being prescribed concurrently with eculizumab or ravulizumab?  Yes  No

Provide documentation of a positive clinical response to therapy:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Attach lab results and other documentation as necessary.**

Prescriber signature (Must match prescriber listed above.)	Date of submission
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**IMPORTANT NOTE:** In evaluating requests for prior authorization the consultant will consider the treatment from the standpoint of medical necessity only. If approval of this request is granted, this does not indicate that the member continues to be eligible for Medicaid. It is the responsibility of the provider who initiates the request for prior authorization to establish by inspection of the member's Medicaid eligibility card and, if necessary by contact with the county Department of Human Services, that the member continues to be eligible for Medicaid.