IOWA Health and Human Services

Request for Prior Authorization
Pegcetacoplan (Empaveli)

FAX Completed Form To
1 (800) 574-2515
Provider Help Desk
1 (877) 776-1567

(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
Prescriber must complete all information above. It must be legible, correct, and complete or form will be returned.		
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**
   a. **Flow cytometry shows detectable glycosylphosphatidylinositol (GPI)-deficient hematopoietic clones or ≥ 10% PNH cells; and**
   b. **History of at least one red blood cell transfusion in the previous 12 months; and**
   c. **Documentation of hemoglobin < 10.5 g/dL; or**
3. **Patient has a diagnosis of complement 3 glomerulopathy (C3G) or immune-complex membraneoproliferative glomerulonephritis (IC-MPGN); and**
   a. **Diagnosis is confirmed on renal biopsy; and**
   b. **Patient is on maximally tolerated dose of an angiotensin converting enzyme inhibitor (ACEI), angiotensin receptor blocker (ARB), and/or sodium glucose cotransporter-2 (SGLT2) inhibitor for at least 3 months prior to starting pegcetacoplan; and**
   c. **Patient has a history of a trial and therapy failure with systemic oral glucocorticoids or mycophenolate mofetil; and**
   d. **Documentation of a baseline urine protein-to-creatinine ratio (UPCR) ≥ 1g/g; and**
   e. **Patient has an eGFR ≥ 30 mL/min/1.73 m_2; and**
4. **For patients under 18 years of age, current weight in kg is provided; and**
5. **Is prescribed by or in consultation with a hematologist or nephrologist; and**
6. **Medication will be administered in the member's home; and**
7. **Member or member's care giver has been properly trained in subcutaneous infusion or subcutaneous injection and prescriber has determined home administration is appropriate; and**
8. **Will not be used with another complement inhibitor or will only be considered for patients switching from one complement to pegcetacoplan based on FDA approved labeling.**

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Initial authorizations will be approved for the FDA approved recommended time period when switching from a different complement inhibitor to verify treatment 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:**
   a. **PNH: e.g., increased or stabilization or hemoglobin levels or reduction in transfusions; or**
   b. **C3G or IC-MPGN: e.g., reduction in UPCR from baseline and eGFR ≥ 30 mL/min/1.73m2; and**
2. **Is not prescribed concurrently with other complement inhibitors.**

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Non-Preferred
☐ Empaveli

Strength	Dosage Instructions	Quantity	Days Supply
_____	_____	_____	_____

Diagnosis: _____

PNH:

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: _____

C3G or IC-MPGN:

Was diagnosis confirmed on renal biopsy? ☐ Yes (attach results) ☐ No

Document trial of maximally tolerated dose of ACEI, ARB, SGLT2 inhibitor for at least 3 months prior to starting pegcetacoplan:

Drug name & dose:_____Trial dates: _____

Document trial and therapy failure with systemic oral glucocorticoids or mycophenolate mofetil:

Drug name & dose:_____Trial dates:_____
Failure reason:_____

Baseline UPCR: _____ Date obtained: _____

Document eGFR: _____ Date obtained: _____

For patients under 18 years of age, document current weight in kg: _____ Date obtained: _____

Is pegcetacoplan being prescribed concurrently with another complement inhibitor?
☐ Yes (provide rationale): _____ ☐ No

Prescriber Specialty: ☐ Hematologist ☐ Nephrologist
☐ Other (specify): _____
If other, note consultation with hematologist or nephrologist: Consultation date: _____
Physician name, specialty & phone: _____

Place of administration: ☐ Member's home ☐ Other: _____

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

Renewal Requests
Is pegcetacoplan being prescribed concurrently with other complement inhibitors? ☐ 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

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 Health and Human Services, that the member continues to be eligible for Medicaid.*