



Request for Prior Authorization
Pegcetacoplan (Empaveli)

(PLEASE PRINT - ACCURACY IS IMPORTANT)

Form with fields for IA Medicaid Member ID #, Patient name, DOB, Patient address, Provider NPI, Prescriber name, Phone, Prescriber address, Fax, Pharmacy name, Address, Phone, 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 >= 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

Strength Dosage Instructions Quantity Days Supply

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.