STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGCETACOPLAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGCETACOPLAN	EMPAVELI	47380		GPI-10 (8580406500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a hematologist
   - The patient has documented confirmation of PNH by flow cytometry demonstrating ALL of the following:
     - At least 2 different GPI-protein deficiencies (e.g., CD55, CD59) on at least 2 cell lineages (e.g., erythrocytes, granulocytes)
     - PNH granulocyte clone size of 10% or greater
   - The patient is NOT concurrently using C5 complement inhibitor therapy (e.g., Soliris, Ultomiris)
   - The patient has tried and failed Soliris or Ultomiris as evidenced by hemoglobin levels <10.5 g/dL directly following at least 3 months of stable dosing

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #200mL per 30 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGCETACOPLAN (Empaveli)** requires the following rule(s) be met for approval:
   A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare disorder that causes red blood cells break)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or given in consultation with a hematologist (blood specialist)
   (Initial denial text continued on next page)

CONTINUED ON NEXT PAGE

PEGCETACOPLAN

INITIAL CRITERIA (CONTINUED)

D. You have documented confirmation of PNH by flow cytometry (type of measurement of physical and chemical qualities of cells) demonstrating ALL of the following:
   1. At least 2 different GPI-protein deficiencies (missing a certain type of protein such as CD55, CD59) on at least 2 cell lineages (types of cells such as erythrocytes, granulocytes)
   2. PNH granulocyte clone size of 10% or greater

E. You have tried and failed Soliris or Ultomiris as evidenced by hemoglobin (type of protein in red blood cells) levels less than 10.5 g/dL, directly following at least 3 months of stable dosing

F. You are not concurrently (at the same time) using C5 complement inhibitor therapy (such as Soliris, Ultomiris)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and meet **ALL** of the following criteria?
   - The patient had a clinical benefit while on Empaveli (e.g., reduction in number of blood transfusions, improvement/stabilization of lactate dehydrogenase (LDH) or hemoglobin levels) compared to baseline (baseline defined as patient condition post treatment with Soliris or Ultomiris)
   - The patient is NOT concurrently using a C5 complement inhibitor therapy (e.g., Soliris, Ultomiris)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #200mL per 30 days.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **PEGCETACOPLAN (Empaveli)** requires the following rule(s) be met for renewal:
   A. You have paroxysmal nocturnal hemoglobinuria (PNH: a rare disorder that causes red blood cells break)
   (Renewal denial text continued on next page)

CONTINUED ON NEXT PAGE

PEGCETACOPLAN

RENEWAL CRITERIA (CONTINUED)

B. You are not concurrently (at the same time) using a C5 complement inhibitor therapy (such as Soliris, Ultomiris)
C. You had a clinical benefit while on Empaveli (such as reduction in number of blood transfusions [adding blood to your body], improvement/stabilization of lactate dehydrogenase [LDH: type of enzyme] or hemoglobin levels [type of protein in red blood cells]) compared to baseline (baseline defined as your condition post treatment with Soliris or Ultomiris)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Empaveli.

REFERENCES

- Empaveli [Prescribing Information]. Waltham, MA: Apellis Pharmaceuticals, Inc., May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/24/22
Created: 05/21
Client Approval: 10/22
P&T Approval: 04/22