SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Empaveli® (pegcetacoplan) (J3490) (Medical)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Maximum Quantity Limits:

- 8 (eight) SQ infusions every 28 days
- Empaveli® 1080 mg/20 mL solution in single-use vials for injection supplied in 8-count cartons

Recommended Dosage:

- Maintenance dose for PNH – 1080 mg twice weekly
- Dosage Adjustment for PNH: For lactate dehydrogenase (LDH) levels > 2 levels ULN, adjust pegcetacoplan dosing regimen to 1080 mg every 3 days. Monitor LDH twice weekly for at least 4 weeks after a dose increase.

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- Dosing for C3G or Primary IC-MPGN:

Patient Body Weight	First dose (infusion volume)	Second dose (infusion volume)	Maintenance dose (infusion volume)
50 kg or higher	1,080 mg (20 mL)	1,080 mg (20 mL)	1,080 mg twice weekly (20 mL)
35 kg to less than 50 kg	648 mg (12 mL)	810 mg (15 mL)	810 mg twice weekly (15 mL)
Less than 35 kg	540 mg (10 mL)	540 mg (10 mL)	648 mg twice weekly (12 mL)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ Diagnosis: Paroxysmal Nocturnal Hemoglobinuria (PNH)

Initial Authorization: 6 months

- ❑ Medication must be prescribed by or in consultation with a hematologist or nephrologist
- ❑ Prescriber must be enrolled in the Empaveli® Risk Evaluation and Mitigation Strategy (REMS) program
- ❑ Member must be 18 years of age or older
- ❑ Member must meet **ONE** of the following:
  - ❑ Empaveli® will be used as switch therapy **AND** member meets **ALL** the following:
    - ❑ Member failed Soliris® or Ultomiris® and must meet renewal criteria
    - ❑ Member does **NOT** have a systemic infection
    - ❑ Member must be vaccinated against encapsulated bacteria (Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B) **at least two weeks prior** to initiation of Empaveli® therapy and revaccinated according to current medical guidelines for vaccine use
    - ❑ Empaveli® will **NOT** be used in combination with other complement inhibitor therapies (e.g., Ultomiris®, Soliris®, Fabhalta®, or Voydeya™)

    OR
  - ❑ Member is treatment-naive **AND** member meets **ALL** the following:
    - ❑ Member must have a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) confirmed by detection of PNH clones of at least 10% by flow cytometry testing **(must submit labs)**
    - ❑ Flow cytometry pathology report must demonstrate at least two (2) different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within two (2) different cell lines from granulocytes, monocytes, erythrocytes **(must submit labs)**

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- ❑ Member has laboratory evidence of significant intravascular hemolysis (i.e. LDH ≥ 1.5 x ULN) **AND** has experienced **ONE** of the following additional indications for therapy **(must submit chart notes and labs)**:
  - ❑ Member is transfusion dependent (defined by having a transfusion within the last 12 months) and has symptomatic anemia
  - ❑ Presence of a thrombotic event (e.g., DVT, PE)
  - ❑ Presence of organ damage secondary to chronic hemolysis (i.e. renal insufficiency, pulmonary insufficiency, or hypertension)
  - ❑ Member is pregnant and potential benefit outweighs potential fetal risk
  - ❑ Member has abdominal pain requiring admission to hospital
- ❑ Member does **NOT** have a systemic infection
- ❑ Member must be administered a meningococcal vaccine **at least two weeks prior** to initiation of Empaveli® therapy and revaccinated according to current medical guidelines for vaccine use

❑ Empaveli® will **NOT** be prescribed concurrently with another FDA approved product prescribed for treatment of PNH (e.g., Bkemv™, Epysqli™, PiaSky®, Ultomiris®, Soliris®, Fabhalta® or Voydeya®)

❑ Diagnosis: Paroxysmal Nocturnal Hemoglobinuria (PNH)

Reauthorization: 6 months

- ❑ Provider attests to an absence of unacceptable toxicity from the drug (e.g. serious meningococcal infections [septicemia and/or meningitis], infusion reactions)
- ❑ Member has experienced positive disease response indicated by at least **ONE** of the following **(check all that apply; results must be submitted to document improvement)**:
  - ❑ Decrease in serum LDH
  - ❑ Stabilization/increase in hemoglobin level
  - ❑ Decrease in packed RBC transfusion requirement
  - ❑ Reduction in thromboembolic events

❑ Diagnosis: Complement 3 Glomerulopathy (C3G) or Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN)

Initial Authorization: 6 months

- ❑ Member is 12 years of age or older and weighs at least 30 kg **(must submit documentation of member's current weight)**
- ❑ Provider is a nephrologist
- ❑ Member has a diagnosis of biopsy-proven, Complement 3 Glomerulopathy (C3G) or Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN) **(must submit biopsy results completed within the last 28 weeks with at least 2+ C3c staining)**

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- ❑ Member is currently established on a stable and maximally tolerated dose of a renin-angiotensin system (RAS) inhibitor (angiotensin converting enzyme [ACE] inhibitor or angiotensin receptor blocker [ARB]), for at least 90 days **(verified by chart notes and/or pharmacy paid claims)**
- ❑ Member's lab test results taken within the last 30 days must be submitted to document **ALL** the following:
  - ❑ Urine protein-to-creatinine ratio ≥ 1.0 g/g
  - ❑ Estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2
- ❑ Member has had an unsuccessful 90-day trial of at least **ONE** of the following therapies for treatment of C3G or primary IC-MPGN **(must submit documentation of therapeutic failure)**:
  - ❑ Corticosteroids (i.e., prednisone, prednisolone) taken along with mycophenolate or mycophenolic acid (i.e., generic Cellcept, Myfortic)
  - ❑ Rituximab (i.e., Rituxan, Ruxience, Truxima)
- ❑ Member will **NOT** be using Empaveli® as concomitant therapy with any of the following: Fabhalta®, Soliris®, Tavneos®, Ultomiris®, Voydeya™ or other complement inhibitor therapies

❑ **Diagnosis: Complement 3 Glomerulopathy (C3G) or Primary Immune-Complex Membranoproliferative Glomerulonephritis (IC-MPGN)**

Reauthorization: 12 months.

- ❑ Member is 12 years of age or older and weighs at least 30 kg **(must submit documentation of member's current weight)**
- ❑ Member's estimated glomerular filtration rate is ≥ 30 mL/min/1.73 m^2 per lab test results taken within the last 30 days **(current lab test results must be submitted for documentation)**
- ❑ Member is currently established on a stable and maximally tolerated dose of a renin-angiotensin system (RAS) inhibitor (angiotensin converting enzyme [ACE] inhibitor or angiotensin receptor blocker [ARB]), for at least 90 days **(verified by chart notes and/or pharmacy paid claims)**
- ❑ Member must have a clinically significant reduction in urine protein-to-creatinine ratio (UPCR) or proteinuria from baseline after initial approval, and reduction or stabilization in UPCR or proteinuria after subsequent approvals **(current lab test results must be submitted for documentation)**
- ❑ Member has **NOT** experienced any treatment-restricting adverse effects (e.g., serious and life-threatening infections)
- ❑ Member will **NOT** be using Empaveli® as concomitant therapy with any of the following: Fabhalta®, Soliris®, Tavneos®, Ultomiris®, Voydeya™ or other complement inhibitor therapies

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Medication being provided by (check applicable box(es) below):

- ❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****