Neighborhood Health Plan OF RHODE ISLAND™
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Empaveli® (pegcetacoplan) Non-Oncology Policy
(Subcutaneous)

Effective Date: 3/1/2026
Review Date: 12/9/2025, 2/10/26
Scope: Medicaid, Commercial, Medicare

For oncology and hematology indications, please refer to Neighborhood's Empaveli Oncology/Hematology Policy

I. Length of Authorization

- Initial: Prior authorization validity will be provided for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 2,160 mg every 7 days

III. Summary of Evidence

Empaveli (pegcetacoplan) is a targeted C3 complement inhibitor indicated for the treatment of adult and pediatric members aged 12 years and older with Complement 3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce proteinuria Evidence for this indication is based on Study APL2-C3G-310, a 26-week randomized, double-blind, placebo-controlled trial enrolling 124 members with biopsy-proven disease on optimized background therapy. The primary efficacy endpoint was the log-transformed ratio of urine protein-to-creatinine ratio (UPCR) at week 26 compared to baseline. Empaveli significantly improved proteinuria compared with placebo. At Week 26, members receiving pegcetacoplan achieved a 68% reduction in UPCR versus placebo (geometric mean ratio 0.33 vs 1.03; $p < 0.0001$). 49% of Empaveli-treated members met the composite renal endpoint of ≥50% reduction in UPCR with stable eGFR, compared with 3% in the placebo arm (odds ratio [95% CI] of 27 [6, 124], $p<0.0001$). Common adverse events include infusion site reactions, pyrexia, nasopharyngitis, influenza, cough, and nausea.

IV. Initial Approval Criteria

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Coverage is provided when ALL of the following are met:

- The member has a diagnosis of C3G confirmed by kidney biopsy OR IC-MPGN confirmed by kidney biopsy; **AND**
- The member is 12 years of age or older; **AND**
- The drug is being prescribed by or in consultation with a nephrologist; **AND**
- The member has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1 g/g **OR** proteinuria greater than or equal to 1.0 g/day; **AND**
- The member's eGFR is greater than or equal to 30 mL/min/1.73 m^2; **AND**
- Member is receiving a stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy (e.g., angiotensin converting enzyme inhibitor [ACEI] or angiotensin II receptor blocker [ARB]) for at least 3 months prior to initiation of therapy, and will continue on maximally tolerated dose of ACEI or ARB therapy with the requested drug, or member has an intolerance or contraindication to RAS inhibitors.; **AND**
- The member will NOT be using the requested agent in combination with Fabhalta (iptacopan); **AND**
- The member does NOT have any FDA labeled contraindications to the requested agent

V. Renewal Criteria

Coverage will be provided when ALL of the following are met:

- The member has a diagnosis of C3G or IC-MPGN; **AND**
- The drug is being prescribed by or in consultation with a nephrologist; **AND**
- The member has had improvements or stabilization with the requested agent as indicated by ONE of the following:
    - Decrease from baseline (prior to treatment with the requested agent) of urine protein-to-creatinine (UPCR) ratio; **OR**
    - Decrease from baseline (prior to treatment with the requested agent) in proteinuria; **AND**
- Member is receiving a stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy (e.g., angiotensin converting enzyme inhibitor [ACEI] or angiotensin II receptor blocker [ARB]), or member has an intolerance or contraindication to RAS inhibitors; **AND**
- Documentation that members eGFR remains ≥30 mL/min/1.73 m^2; **AND**
- The member will NOT be using the requested agent in combination with Fabhalta (iptacopan); **AND**
- The member does NOT have any FDA labeled contraindications to the requested agent

VI. Dosage/Administration

<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>C3G and IC-MPGN</td><td><u>Adults (18 years and older)</u>:
– The recommended dose of Empaveli is 1,080 mg by subcutaneous infusion twice weekly.
<u>Pediatric Members (12 years to less than 18 years of age)</u>:
– Administer Empaveli subcutaneously twice weekly based upon body weight according to the dosing schedule in the table below.
<table>
<tr><th>Member Body Weight</th><th>First dose (infusion volume)</th><th>Second dose (infusion volume)</th><th>Maintenance dose (infusion volume)</th></tr>
<tr><td>≥ 50 kg</td><td>1,080 mg (20 mL)</td><td>1,080 mg (20 mL)</td><td>1,080 mg twice weekly (20 mL)</td></tr>
<tr><td>35 kg to < 50 kg</td><td>648 mg (12 mL)</td><td>810 mg (15 mL)</td><td>810 mg twice weekly (15 mL)</td></tr>
<tr><td>< 35 kg</td><td>540 mg (10 mL)</td><td>540 mg (10 mL)</td><td>648 mg twice weekly (12 mL)</td></tr>
</table></td></tr>
<tr><td colspan="2">– Empaveli is for subcutaneous administration using a commercially available infusion pump with a reservoir of at least 20 mL or with Empaveli single-use, disposable on body injector.
– Empaveli is intended for use under the guidance of a healthcare professional. After proper training on preparation and administration, a member may self-administer, or the member's caregiver may administer Empaveli, if a healthcare provider determines that it is appropriate.</td></tr>
</table>

VII. Billing Code/Availability Information

<u>HCPCS Code(s):</u>

- J7799 – Noc drugs, other than inhalation drugs, administered through dme
- C9399 – Unclassified drugs or biologicals (Hospital Outpatient Use Only)
- J3490 – Unclassified drugs

<u>NDC:</u>

- Empaveli 1,080 mg/20 mL solution in single-dose vials for subcutaneous infusion: 73606-0010-xx

VIII. References

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]
N00.A	Acute nephritic syndrome with C3 glomerulonephritis
N00.5	Acute nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
N00.6	Acute nephritic syndrome with dense deposit disease
N01.A	Rapidly progressive nephritic syndrome with C3 glomerulonephritis
N01.5	Rapidly progressive nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
N01.6	Rapidly progressive nephritic syndrome with dense deposit disease
N02.A	Recurrent and persistent hematuria with C3 glomerulonephritis
N02.5	Recurrent and persistent hematuria with diffuse mesangiocapillary glomerulonephritis
N02.6	Recurrent and persistent hematuria with dense deposit disease
N03.A	Chronic nephritic syndrome with C3 glomerulonephritis
N03.5	Chronic nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
N03.6	Chronic nephritic syndrome with dense deposit disease
N04.A	Nephrotic syndrome with C3 glomerulonephritis
N04.5	Nephrotic syndrome with diffuse mesangiocapillary glomerulonephritis
N04.6	Nephrotic syndrome with dense deposit disease

ICD-10	ICD-10 Description
N05.A	Unspecified nephritic syndrome with C3 glomerulonephritis
N05.5	Unspecified nephritic syndrome with diffuse mesangiocapillary glomerulonephritis
N05.6	Unspecified nephritic syndrome with dense deposit disease
N06.A	Isolated proteinuria with C3 glomerulonephritis
N06.5	Isolated proteinuria with diffuse mesangiocapillary glomerulonephritis
N06.6	Isolated proteinuria with dense deposit disease
N07.A	Hereditary nephropathy, not elsewhere classified with C3 glomerulonephritis
N07.5	Hereditary nephropathy, not elsewhere classified with diffuse mesangiocapillary glomerulonephritis
N07.6	Hereditary nephropathy, not elsewhere classified with dense deposit disease

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outmember (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:

Empaveli was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Empaveli according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature.

Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.