Clinical Policy: Pegcetacoplan (Empaveli, Syfovre)

Reference Number: CP.PHAR.524
Effective Date: 05.14.21
Last Review Date: 08.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Pegcetacoplan (Empaveli®, Syfovre®) is a C3/C3b complement inhibitor.

FDA Approved Indication(s)

Empaveli is indicated for the treatment of:

- Adult patients with paroxysmal nocturnal hemoglobinuria (PNH)
- Adult and pediatric patients aged 12 years and older with C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN), to reduce proteinuria

Syfovre is indicated for the treatment of adult patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Empaveli and Syfovre are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Paroxysmal Nocturnal Hemoglobinuria (must meet all)**:**

1. Diagnosis of PNH;
2. Request is for Empaveli;
3. Prescribed by or in consultation with a hematologist;
4. Age ≥ 18 years;
5. Flow cytometry shows detectable glycosylphosphatidylinositol (GPI)-deficient hematopoietic clones or ≥ 10% PNH cells;
6. Documentation of hemoglobin < 10.5 g/dL;
7. Empaveli is not prescribed concurrently with either of the following (a and b):
   a. Syfovre;
   b. Another FDA-approved product for PNH (e.g., Soliris®, Ultomiris®, Fabhalta®, Voydeya™, Bkemv™, Epysqli®, PiaSky®), unless the member is in a 4-week period of cross-titration between Soliris/Bkemv/Epysqli and Empaveli;*
   **Provider must submit attestation of the presence or absence of concomitant Soliris/Bkemv/Epysqli therapy*

8. Dose does not exceed 2,160 mg per week or 1,080 mg every 3 days (total 10 doses per month) with documentation of a lactate dehydrogenase (LDH) level greater than 2 times the upper limit of normal (ULN).

Approval duration: 6 weeks *(if within cross-titration period with Soliris)*, or 6 months

B. C3 Glomerulopathy, Primary Immune-Complex Membranoproliferative Glomerulonephritis (must meet all)**:**

1. Diagnosis of one of the following confirmed via kidney biopsy (a or b):
   a. C3G;
   b. Primary IC-MPGN, and member does not have recurrent disease following kidney transplant;
2. Request is for Empaveli;
3. Prescribed by or in consultation with a nephrologist;
4. Age ≥ 12 years;
5. Documentation of both of the following (a and b):
   a. Urine protein-to-creatinine ratio (UPCR) ≥ 1 g/g;
   b. Estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m^2;
6. Failure of at least a 12-week trial of a renin-angiotensin-aldosterone system (RAAS) inhibitor (e.g., irbesartan, losartan, lisinopril, benazepril) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (*see Appendix D*);*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
7. Empaveli is not prescribed concurrently with either of the following (a and b):
   a. Syfovre;
   b. Another FDA-approved product for C3G or IC-MPGN (e.g., Fabhalta);
8. Dose does not exceed one of the following (a, b, or c):
   a. Adults and pediatric members weighing ≥ 50 kg: 1,080 mg twice per week;
   b. Pediatric members weighing 35 kg to < 50 kg: 810 mg twice per week;
   c. Pediatric members weighing < 35 kg: 648 mg twice per week.

Approval duration: 6 months

C. Geographic Atrophy (must meet all)**:**

1. Diagnosis of GA secondary to AMD;
2. GA has all of the following characteristics confirmed on fundus autofluorescence imaging (a, b, c, and d):
   a. Total GA area ≥ 2.5 and ≤ 17.5 mm^2 (1 and 7 disk areas [DA] respectively);
   b. If GA is multifocal, at least one focal lesion ≥ 1.25 mm^2 (0.5 DA);
   c. GA lesion(s) are not contiguous with any areas of peripapillary atrophy;
   d. Presence of hyperautofluorescence in the junctional zone of GA;
3. Request is for Syfovre;
4. Prescribed by or in consultation with an ophthalmologist;
5. Age ≥ 60 years;
6. Best corrected visual acuity (BCVA) of 24 letters or better on Early Treatment Diabetic Retinopathy Study (ETDRS) charts (approximately 20/320 Snellen equivalent);

7. Member does not have either of the following (a and b):
   a. Diagnosis of any condition that may cause GA, including but not limited to pathologic myopia, Stargardt disease, cone rod dystrophy, and toxic maculopathies like Plaquenil maculopathy;
   b. History of or active choroidal neovascularization (CNV) in the eye(s) affected by GA;
8. Syfovre is not prescribed concurrently with Empaveli;
9. Dose does not exceed 15 mg (0.1 mL of 150 mg/mL solution) in each affected eye every 25 days.

Approval duration: 12 months

D. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Paroxysmal Nocturnal Hemoglobinuria (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Request is for Empaveli;
3. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in <u>any</u> of the following parameters (a – f):
   a. Improved measures of intravascular hemolysis or extravascular hemolysis (e.g., normalization of lactate dehydrogenase, reduced absolute reticulocyte count, reduced bilirubin);
   b. Reduced need for red blood cell transfusions;
   c. Increased or stabilization of hemoglobin levels;
   d. Less fatigue;

e. Improved health-related quality of life;
f. Fewer thrombotic events;

4. Empaveli is not prescribed concurrently with either of the following (a and b):
   a. Syfovre;
   b. Another FDA-approved product for PNH (e.g., Soliris, Ultomiris, Fabhalta, Voydeya, Bkemv, Epysqli, PiaSky);
5. If request is for a dose increase, new dose does not exceed 2,160 mg per week or 1,080 mg every 3 days (total 10 doses per month) with documentation of an LDH level greater than 2 times the ULN.

Approval duration: 12 months

B. C3 Glomerulopathy, Primary Immune-Complex Membranoproliferative Glomerulonephritis (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Request is for Empaveli;
3. Member is responding positively to therapy as evidenced by one of the following (a or b):
   a. Decrease in UPCR from baseline;
   b. Reduction of proteinuria as evidence by a lower total urine protein per day from baseline;
4. Empaveli is not prescribed concurrently with either of the following (a and b):
   a. Syfovre;
   b. Another FDA-approved product for C3G or IC-MPGN (e.g., Fabhalta);
5. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
   a. Adults and pediatric members weighing ≥ 50 kg: 1,080 mg twice per week;
   b. Pediatric members weighing 35 kg to < 50 kg: 810 mg twice per week;
   c. Pediatric members weighing < 35 kg: 648 mg twice per week.

Approval duration: 12 months

C. Geographic Atrophy (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Request is for Syfovre;
3. Member is responding positively to therapy;
4. Syfovre is not prescribed concurrently with Empaveli;

5. If request is for a dose increase, new dose does not exceed 15 mg (0.1 mL of 150 mg/mL solution) in each affected eye every 25 days.

Approval duration: 12 months

D. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACEI: angiotensin-converting enzyme inhibitor
AMD: age-related macular degeneration
ARB: angiotensin receptor blocker
BCVA: best corrected visual acuity
C3G: C3 glomerulopathy
CNV: choroidal neovascularization
DA: disk area
ETDRS: Early Treatment Diabetic Retinopathy Study
FDA: Food and Drug Administration
GA: geographic atrophy
GPI: glycosylphosphatidylinositol
IC-MPGN: immune-complex membranoproliferative glomerulonephritis
LDH: lactate dehydrogenase
PNH: paroxysmal nocturnal hemoglobinuria
RAAS: renin-angiotensin-aldosterone system
REMS: Risk Evaluation and Mitigation Strategy
ULN: upper limit of normal

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Maximum Dose
Angiotensin-converting enzyme inhibitors (ACEIs)		
benazepril (Lotensin®)	Various	80 mg/day
captopril (Capoten®)	Various	450 mg/day
enalapril (Vasotec®, Epaned®)	Various	40 mg/day
fosinopril (Monopril®)	Various	80 mg/day
lisinopril (Prinivil®, Zestril®, Qbrelis®)	Various	80 mg/day
moexipril (Univasc®)	Various	30 mg/day
perindopril (Aceon®)	Various	16 mg/day
quinapril (Accupril®)	Various	80 mg/day
ramipril (Altace®)	Various	20 mg/day
trandolapril (Mavik®)	Various	8 mg/day
Angiotensin receptor blockers (ARBs)		
azilsartan (Edarbi®)	Various	80 mg/day
candesartan (Atacand®)	Various	32 mg/day
eprosartan (Teveten®)	Various	900 mg/day
irbesartan (Avapro®)	Various	300 mg/day
losartan (Cozaar®)	Various	100 mg/day
olmesartan (Benicar®)	Various	40 mg/day
telmisartan (Micardis®)	Various	80 mg/day
valsartan (Diovan®)	Various	320 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Empaveli: hypersensitivity to pegcetacoplan or any of the excipients; for initiation in patients with unresolved serious infection caused by encapsulated bacteria including *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type B
  - Syfovre: ocular or periocular infections; active intraocular inflammation; hypersensitivity
- Boxed warning(s):
  - Empaveli: serious infections caused by encapsulated bacteria; Empaveli is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS)
  - Syfovre: none reported

Appendix D: General Information

- The 2021 Kidney Disease Improving Global Outcomes (KDIGO) glomerular disease guideline recommends supportive therapy with a RAAS inhibitor (ACEI or ARB) as first

line for all patients with glomerulonephritis (such as C3G and IC-MPGN) and proteinuria.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Empaveli*	PNH	1,080 mg SC twice weekly For patients switching from Soliris/Bkemv/Epysqli, initiate Empaveli while continuing Soliris/Bkemv/Epysqli at its current dose. After 4 weeks, discontinue Soliris/Bkemv/Epysqli before continuing on monotherapy with Empaveli. For patients switching from Ultomiris, initiate Empaveli no more than 4 weeks after the last dose of Ultomiris. For LDH levels > 2x ULN, adjust the dosing regimen to 1,080 mg every three days.	1,080 mg/dose
	C3G, primary IC-MPGN	Adults and pediatric members weighing ≥ 50 kg: 1,080 mg SC twice weekly Pediatric members weighing 35 kg to < 50 kg: 810 mg SC twice weekly Pediatric members weighing < 35 kg: 648 mg SC twice weekly	See regimen
Syfovre	GA	15 mg (0.1 mL of 150 mg/mL solution) via intravitreal injection to each affected eye once every 25 to 60 days	15 mg/25 days

**Empaveli may be administered via a commercially available infusion pump or the Empaveli on body injector*

VI. Product Availability

Drug Name	Availability
Empaveli	Single-dose vial for subcutaneous injection: 1,080 mg/20 mL
Syfovre	Single-dose vial for intravitreal injection: 150 mg/mL

VII. References

1. Empaveli Prescribing Information. Waltham, MA: Apellis Pharmaceuticals, Inc.; July 2025. Available at: https://empavelihcp.com/. Accessed August 7, 2025.
2. Wong R, Pullon H, Deschatelets P, et al. Inhibition of C3 with APL-2 results in normalization of markers of intravascular and extravascular hemolysis in subjects with paroxysmal nocturnal hemoglobinuria (PNH). Poster presented at: American Society of Hematology (ASH). 2018.

3. Hillmen P, Szer J, Weitz IC, et al. Pegcetacoplan versus eculizumab in paroxysmal nocturnal hemoglobinuria. NEJM March 2021;384:1028-37.
4. Bhak RY, Mody-Patel N, Baver SB, et al. Comparative effectiveness of pegcetacoplan versus ravulizumab in patients with paroxysmal nocturnal hemoglobinuria previously treated with eculizumab: a matching-adjusted indirect comparison. Abstract 2581. Presented at the 62nd American Society of Hematology Annual Meeting and Exposition, Dec 2-11, 2020.
5. Parker C, Omine M, Richards S, et al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood 2005; 106(12):3699-3709. Doi:10.1182/blood-2005-04-1717.
6. Apellis Pharmaceuticals, Inc. Study of pegcetacoplan (APL-2) therapy in patients with geographic atrophy (FILLY). ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT02503332. Accessed May 1, 2025.
7. Liao DS, Grossi FV, El Mehdi D, et al. Complement C3 inhibitor pegcetacoplan for geographic atrophy secondary to age-related macular degeneration: A randomized phase 2 trial. Ophthalmology. 2020; 127(2): 186-195.
8. Apellis Pharmaceuticals, Inc. Study to compare the efficacy and safety of intravitreal APL-2 therapy with sham injections in patients with geographic atrophy (GA) secondary to age-related macular degeneration (DERBY). ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT03525600. Accessed May 1, 2025.
9. Apellis Pharmaceuticals, Inc. A study to compare the efficacy and safety of intravitreal APL-2 therapy with sham injections in patients with geographic atrophy (GA) secondary to age-related macular degeneration (OAKS). ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/show/NCT03525613. Accessed May 1, 2025.
10. Goldberg R, Heier JS, Wyoff CC, et al. Abstract: Efficacy of intravitreal pegcetacoplan in patients with geographic atrophy (GA): 12-month results from the phase 3 OAKS and DERBY studies. Investigative Ophthalmology & Visual Science. 2022; 63(7): 1500.
11. Apellis Pharmaceuticals, Inc. Apellis announces pegcetacoplan showed continuous and clinically meaningful effects at month 18 in phase 3 DERBY and OAKS studies for geographic atrophy (GA). News release published March 16, 2022. Available at: https://investors.apellis.com/news-releases/news-release-details/apellis-announces-pegcetacoplan-showed-continuous-and-clinically. Accessed May 1, 2025.
12. American Academy of Ophthalmology Retina/Vitreous Committee. Preferred Practice Pattern® Guidelines. Age-Related Macular Degeneration. San Francisco, CA: American Academy of Ophthalmology; 2024. Published February 2025. Available at: https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp. Accessed May 1, 2025.
13. Syfovre Prescribing Information. Waltham, MA: Apellis Pharmaceuticals, Inc.; December 2024. Available at: https://syfovre.com. Accessed April 16, 2025.
14. Regillo CD, Nijm LM, Shechtman DL, et al. Considerations for the identification and management of geographic atrophy: Recommendations from an expert panel. Clinical Ophthalmology. 2024; 18: 325-335.
15. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 clinical practice guideline for the management of glomerular diseases. Kidney Int. 2021 Oct;100(4S):S1-S276. doi: 10.1016/j.kint.2021.05.021.
16. Vivarelli M, Barratt J, Beck LH, et al. The role of complement in kidney disease: Conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. Kidney International. 2024; 106: 369-391.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2781	Injection, pegcetacoplan, intravitreal, 1 mg
J7799	Noc drugs, other than inhalation drugs, administered through dme

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	01.05.21	02.21
Drug is now FDA-approved – criteria updated per FDA labeling: modified restriction against concomitant use of Empaveli with Soliris by making an exception for the initial 4-week cross-titration phase; references reviewed and updated.	05.18.21	08.21
1Q 2022 annual review: increased the maximum recommended dose to accommodate patients who experience increased LDH levels, per dosing recommendations in the Empaveli PI; removed the requirement for initial approval for at least one RBC transfusion in the last 12 months since 25% of the patients in the PEGASUS trial had zero past transfusions and data from the trial did not show a difference in Empaveli effect for those patients; references reviewed and updated.	11.16.21	02.22
Added pre-emptive criteria for intravitreal pegcetacoplan (APL-2) for GA secondary to AMD. Template changes applied to other diagnoses/indications and continued therapy section.	07.27.22	11.22
1Q 2023 annual review: no significant changes; revised tentative product availability for APL-2 from 15 mg/1 mL to 15 mg/0.1 mL per manufacturer; references reviewed and updated.	11.03.22	02.23
RT1: Intravitreal pegcetacoplan (Syfovre) is now FDA approved – GA criteria updated per FDA labeling: revised maximum dosing frequency from every month to every 25 days; clarified that CNV exclusion applies only to the eye(s) affected by GA per OAKS/DERBY study design; references reviewed and updated.	04.11.23	05.23
3Q 2023 annual review: no significant changes; added drug-specific HCPCS code for Syfvore; references reviewed and updated.	05.08.23	08.23
RT4: per updated Empaveli label, updated dosing information in Section V to include administration using the Empaveli on body injector. Added HCPCS code J2781.	10.16.23	
Added HCPCS code [J2781], removed inactive HCPCS code [C9151]	10.27.23	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2024 annual review: for PNH, added Fabhalta, Voydeya, and Bkemv to the list of therapies that Empaveli should not be prescribed concurrently with; for GA, clarified that diagnostic characteristics must be confirmed on fundus autofluorescence imaging per health plan request and in alignment with pivotal study design; revised Empaveli contraindications in Appendix C per updated prescribing information; references reviewed and updated.	05.15.24	08.24
3Q 2025 annual review: for PNH, added Epysqli and PiaSky to the list of therapies that Empaveli should not be prescribed concurrently with, added improvement of extravascular hemolysis as an example of positive response to therapy, and revised continued approval duration from 6 to 12 months as PNH is a chronic condition; updated Syfovre contraindications in Appendix C to include hypersensitivity per updated prescribing information; references reviewed and updated.	05.01.25	08.25
RT4: added criteria for new FDA-approved indication of C3G/primary IC-MPGN for Empaveli.	08.07.25	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or

regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.