Clinical Policy: Bempedoic Acid (Nexletol), Bempedoic Acid/Ezetimibe (Nexlizet)

Reference Number: CP.PMN.237
Effective Date: 09.01.20
Last Review Date: 02.25
Line of Business: Commercial, HIM, Medicaid Revision Log

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

Description

The following are adenosine triphosphate-citrate lyase (ACL) inhibitors requiring prior authorization: bempedoic acid (Nexletol®) and bempedoic acid/ezetimibe (Nexlizet®). Nexlizet contains ezetimibe, which is a cholesterol absorption inhibitor.

FDA Approved Indication(s)

Nexletol and Nexlizet are indicated:

- As an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH)
- To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD) or a high risk for a CVD event but without established CVD

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 Nexletol and Nexlizet are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Primary Hyperlipidemia (including HeFH) and Cardiovascular Disease (including ASCVD) (must meet all)**:**

1. Diagnosis of one of the following (a, b, or c):
   a. **CVD (including atherosclerotic cardiovascular disease [ASCVD]** and **high risk for a CVD event)** as evidenced by one of the following (i or ii):
      i. ASCVD as evidenced by a history of any one of the following conditions (1 - 7):
         1) Acute coronary syndromes;
         2) Clinically significant coronary heart disease (CHD) diagnosed by invasive or noninvasive testing (such as coronary angiography, stress test using treadmill, stress echocardiography, or nuclear imaging);
         3) Coronary or other arterial revascularization;

4) Myocardial infarction;
5) Peripheral arterial disease presumed to be of atherosclerotic origin;
6) Stable or unstable angina;
7) Stroke or transient ischemic attack (TIA);

ii. High risk for a CVD event defined as one of the following (1-4):
1) Type 1 or type 2 diabetes mellites and one of the following (a or b):
a) If female, age > 65 years;
b) If male, age > 60 years;
2) A Reynolds risk score > 30% (*see Appendix J*);
3) A Systematic Coronary Risk Evaluation (SCORE) score > 7.5% over 10 years (*see Appendix K*);
4) A coronary artery calcium score > 400 Agatston units;

b. **HeFH,** and both of the following (i and ii):
i. Baseline LDL-C (prior to any lipid-lowering pharmacologic therapy) was one of the following (1 or 2):
1) If age < 20 years: ≥ 160 mg/dL;
2) If age ≥ 20 years: ≥ 190 mg/dL;
ii. HeFH diagnosis is confirmed by one of the following (1 or 2):
1) World Health Organization (WHO)/Dutch Lipid Network familial hypercholesterolemia diagnostic criteria score of > 8 as determined by requesting provider (*see Appendix D*);
2) Definite diagnosis per Simon Broome criteria (*see Appendix D*);

c. **Primary hyperlipidemia that is not HeFH,** and both of the following (i and ii):
i. Documentation of one of the following (1 or 2):
1) Presence of a genetically mediated form of primary hyperlipidemia as evidenced by confirmatory genetic testing results;
2) A diagnosis of secondary hyperlipidemia has been ruled out with absence of all of the following potential causes of elevated cholesterol (a-f):
a) Poor diet;
b) Hypothyroidism;
c) Obstructive liver disease;
d) Renal disease;
e) Nephrosis;
f) Medications that have had a clinically relevant contributory effect on the current degree of this member's elevated lipid levels including, but not limited to: glucocorticoids, sex hormones, antipsychotics, antiretrovirals, immunosuppressive agents, retinoic acid derivatives;
ii. Baseline LDL-C (prior to any lipid-lowering pharmacologic therapy) was ≥ 190 mg/dL;

2. Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist;
3. Age ≥ 18 years;
4. For members on statin therapy, both of the following (a and b):
a. Nexletol or Nexlizet is prescribed in conjunction with a statin at the maximally tolerated dose;

   b. Member has been adherent for at least the last 8 weeks to maximally tolerated doses of one of the following statin regimens (i or ii):
      i. A high intensity statin (*see Appendix E*);
      ii. A moderate or low intensity statin (*see Appendix E*), and member has one of the following (1 or 2):
         1) Previous use of one high-intensity statin (i.e., atorvastatin ≥ 40 mg daily; rosuvastatin ≥ 20 mg daily [as a single-entity or as a combination product]) for a minimum of 8 weeks continuously and LDL-C remained ≥ 70 mg/dL;
         2) Member has tried both rosuvastatin and atorvastatin and has experienced skeletal-muscle related symptoms on both agents which also resolved upon discontinuation;
5. For members not on statin therapy, member meets one of the following (a or b):
   a. Statin therapy is contraindicated per Appendix F;
   b. For members who are statin intolerant, both of the following (i and ii):
      i. Member has tried at least two statins, one of which must be hydrophilic (pravastatin, fluvastatin, or rosuvastatin);
      ii. Member meets one of the following (1 or 2):
         1) Member has documented statin risk factors (*see Appendix G*);
         2) Member is statin intolerant due to statin-associated muscle symptoms (SAMS) and meets both of the following (a and b):
            a) Documentation of intolerable SAMS persisting at least two weeks, which disappeared with discontinuing the statin therapy and recurred with a statin re-challenge;
            b) Documentation of re-challenge with titration from lowest possible dose and/or intermittent dosing frequency (e.g., 1 to 3 times weekly);
6. Member has been adherent to ezetimibe therapy used concomitantly with a statin at the maximally tolerated dose for at least the last 8 weeks, unless contraindicated per Appendix F or member has a history of ezetimibe intolerance (e.g., associated diarrhea or upper respiratory tract infection);
7. For Nexletol, documentation that ezetimibe will be prescribed concurrently for as long as Nexletol is prescribed, unless contraindicated per Appendix F or member has a history of ezetimibe intolerance (e.g., associated diarrhea or upper respiratory tract infection);
8. Documentation of recent (within the last 60 days) LDL-C of one of the following (a or b):
   a. If member has ASCVD (i or ii):
      i. ≥ 70 mg/dL;
      ii. ≥ 55 mg/dL, and member is at very high risk (*see Appendix I*);
   b. If member has primary hyperlipidemia (including HeFH), CVD, or is at high risk for CVD: ≥ 100 mg/dL;
9. Dose does not exceed either of the following (a or b):
   a. Nexletol: 180 mg per day;
   b. Nexlizet: bempedoic acid 180 mg/ezetimibe 10 mg per day.

Approval duration: 12 months

B. 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. All Indications in Section I (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. If statin tolerant, documentation of adherence to a statin at the maximally tolerated dose;
3. For Nexletol, documentation that ezetimibe is being prescribed concurrently with Nexletol, unless a contraindication or adverse event to ezetimibe has developed;
4. Member is responding positively to therapy as evidenced by lab results within the last 3 months showing an LDL-C reduction since initiation of Nexletol or Nexlizet therapy;
5. If request is for a dose increase, new dose does not exceed either of the following (a or b):
   a. Nexletol: 180 mg per day;
   b. Nexlizet: bempedoic acid 180 mg/ezetimibe 10 mg per day.

Approval duration: 12 months

B. 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

ASCVD: atherosclerotic cardiovascular disease
CHD: coronary heart disease
CVD: cardiovascular disease
ESC: European Society of Cardiology
FDA: Food and Drug Administration
HeFH: heterozygous familial hypercholesterolemia
LDL-C: low density lipoprotein cholesterol
SAMS: statin-associated muscle symptoms
SCORE: Systematic Coronary Risk Evaluation
TIA: transient ischemic attack
WHO: World Health Organization

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	Dose Limit/Maximum Dose
ezetimibe (Zetia®)	10 mg PO QD	10 mg/day
atorvastatin (Lipitor®)	40 mg PO QD	80 mg/day
rosuvastatin (Crestor®)	5 - 40 mg PO QD	40 mg/day
pravastatin (Pravachol®)	10 – 80 mg PO QD	80 mg/day
fluvastatin (Lescol®)	20 – 80 mg Po QD	80 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):
  - Nexletol: history of a serious hypersensitivity reaction to bempedoic acid or any of the excipients in Nexletol

- Nexlizet: known hypersensitivity to ezetimibe or bempedoic acid or any of the excipients in Nexlizet
- Boxed warning(s): none reported

Appendix D: Criteria for Diagnosis of HeFH

- Dutch Lipid Clinic Network criteria for Familial Hypercholesterolemia (FH)

FH Criteria	Points	Member's Score†
Family History		
First-degree relative with known premature* coronary and vascular disease	1	Place highest score here (0, 1 or 2)
First-degree relative with known LDL-C level above the 95th percentile	1	
First-degree relative with tendinous xanthomata and/or arcus cornealis	2	
Children aged < 18 years with LDL-C level above the 95th percentile	2	
Clinical History		
Patient with premature* coronary artery disease	2	Place highest score here (0, 1 or 2)
Patient with premature* cerebral or peripheral vascular disease	1	
Physical Examination		
Tendinous xanthomata	6	Place highest score here (0, 4 or 6)
Arcus cornealis prior to age 45 years	4	
Cholesterol Levels - mg/dL (mmol/liter)		
LDL-C ≥ 330 mg/dL (≥ 8.5)	8	Place highest score here (0, 1, 3, 5 or 8)
LDL-C 250 – 329 mg/dL (6.5 – 8.4)	5	
LDL-C 190 – 249 mg/dL (5.0 – 6.4)	3	
LDL-C 155 – 189 mg/dL (4.0 – 4.9)	1	
DNA Analysis		
Functional mutation in the *LDLR, apo B* or *PCSK9* gene	8	Place score here (0 or 8)
TOTAL SCORE	Definite FH: > 8	Place total score here __

*Premature – men < 55 years or women < 60 years
†Choose the highest score from each of the five categories and then add together for a total score. The five categories are 1) Family History, 2) Clinical History, 3) Physical Examination, 4) Cholesterol Levels, and 5) DNA Analysis.

- Simon Broome Register Group Definition of Definite FH (meets 1 and 2):
  1. One of the following (a or b):
     a. Total cholesterol level above 7.5 mmol/l (290 mg/dl) in adults or a total cholesterol level above 6.7 mmol/l (260 mg/dl) for children under 16;
     b. LDL levels above 4.9 mmol/l (190 mg/dl) in adults (4.0 mmol/l in children) (either pre-treatment or highest on treatment);

2. One of the following (a or b):
   a. Tendinous xanthomas in patient or relative (parent, child, sibling, grandparent, aunt, uncle);
   b. DNA-based evidence of an LDL receptor mutation or familial defective apo B-100

- High and Moderate Risk of ASCVD:
  - Patients with high risk of ASCVD include the following:
    - History of clinical atherosclerotic cardiovascular disease (as defined in section II)
    - Diabetes with an estimated 10-year ASCVD risk ≥ 7.5% for adults 40-75 years of age
    - Untreated LDL ≥ 190 mg/dL
  - Patients with moderate risk of ASCVD include the following:
    - Diabetes with an estimated 10-year ASCVD risk < 7.5% for adults 40-75 years of age
    - Estimated 10-year ASCVD risk ≥ 5% for adults 40-75 years of age
  - The calculator for the 10-year ASCVD risk estimator can be found here: http://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/calculate/estimate. Information needed to complete the ASCVD Risk Estimator include: gender, race (white, African American, other), systolic blood pressure, history of diabetes, age, total cholesterol, HDL-cholesterol, treatment for hypertension, smoking history or status, and concurrent statin or aspirin therapy.

Appendix E: High, Moderate, and Low Intensity Daily Statin Therapy for Adults

High Intensity Statin Therapy ***Daily dose shown to lower LDL-C, on average, by approximately ≥ 50%***
• Atorvastatin 40-80 mg • Rosuvastatin 20-40 mg
Moderate Intensity Statin Therapy ***Daily dose shown to lower LDL-C, on average, by approximately 30% to 50%***
• Atorvastatin 10-20 mg • Fluvastatin XL 80 mg • Fluvastatin 40 mg BID • Lovastatin 40 mg • Pitavastatin 1-4 mg • Pravastatin 40-80 mg • Rosuvastatin 5-10 mg • Simvastatin 20-40 mg
Low Intensity Statin Therapy ***Daily dose shown to lower LDL-C, on average, by < 30%***
• Simvastatin 10 mg • Pravastatin 10-20 mg • Lovastatin 20 mg • Fluvastatin 20-40 mg

Appendix F: Statin and Ezetimibe Contraindications

Statins
• Decompensated liver disease (development of jaundice, ascites, variceal bleeding, encephalopathy) • Laboratory-confirmed acute liver injury or rhabdomyolysis resulting from statin treatment • Pregnancy*, actively trying to become pregnant, or nursing • Immune-mediated hypersensitivity to the HMG-CoA reductase inhibitor drug class (statins) as evidenced by an allergic reaction occurring with at least TWO different statins
Ezetimibe
• Moderate or severe hepatic impairment [Child-Pugh classes B and C] • Hypersensitivity to ezetimibe (e.g., anaphylaxis, angioedema, rash, urticaria)

**In July 2021, the FDA requested removal of the contraindication against use of statins in pregnant women. Because the benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients, contraindicating these drugs in all pregnant women is not appropriate. https://www.fda.gov/safety/medical-product-safety-information/statins-drug-safety-communication-fda-requests-removal-strongest-warning-against-using-cholesterol*

Appendix G: Statin Risk Factors

Statin Risk Factors
• Multiple or serious comorbidities, including impaired renal or hepatic function • Unexplained alanine transaminase (ALT) elevations > 3 times upper limit of normal, or active liver disease • Concomitant use of drugs adversely affecting statin metabolism • Age > 75 years, or history of hemorrhagic stroke • Asian ancestry

Appendix H: General Information

- Patients should remain on concomitant therapy with a statin if tolerated due to the established long term cardiovascular benefits.
- The diagnosis of SAMS is often on the basis of clinical criteria. Typical SAMS include muscle pain and aching (myalgia), cramps, and weakness. Symptoms are usually bilateral and involve large muscle groups, including the thigh, buttock, back, and shoulder girdle musculature. In contrast, cramping is usually unilateral and may involve small muscles of the hands and feet. Symptoms may be more frequent in physically active patients. Symptoms often appear early after starting stain therapy or after an increase in dose and usually resolve or start to dissipate within weeks after cessation of therapy, although it may take several months for symptoms to totally resolve. Persistence of symptoms for more than 2 months after drug cessation should prompt a search for other causes or for underlying muscle disease possibly provoked by statin therapy. The reappearance of symptoms with statin rechallenge and their disappearance with drug cessation offers the best evidence that the symptoms are truly SAMS.
- Pravastatin, fluvastatin, and rosuvastatin are hydrophilic statins which have been reported to confer fewer adverse drug reactions than lipophilic statins.

Appendix I: Criteria for Defining Patients at Very High Risk of Future ASCVD Events[9]
Very high risk is defined as having either a history of multiple major ASCVD events **OR** 1 major ASCVD event and multiple high-risk conditions:

- Major ASCVD events:
  - Recent acute coronary syndrome (within the past 12 months)
  - History of myocardial infarction (other than recent acute coronary syndrome event listed above)
  - History of ischemic stroke
  - Symptomatic peripheral artery disease (history of claudication with ankle-brachial index < 0.85 or previous revascularization or amputation)
- High-risk conditions:
  - Age ≥ 65 years
  - FH
  - History of prior coronary artery bypass surgery or percutaneous coronary intervention outside of the major ASCVD event(s)
  - Diabetes
  - Hypertension
  - Chronic kidney disease (estimated glomerular filtration rate [eGFR] 15-59 mL/min/1.73 m^2)
  - Current tobacco smoking
  - Persistently elevated LDL-C (LDL-C ≥ 100 mg/dL [≥ 2.6 mmol/L]) despite maximally tolerated statin therapy and ezetimibe
  - History of congestive heart failure

Appendix J: Reynolds Risk Score[14]

- Reynolds Risk Score is developed to calculate the 10-year cardiovascular risk in women. The score is classified into four categories: low risk, low to moderate risk, moderate to high risk, and high risk.
  - < 5%: low CVD risk
  - 5% to < 10%: low to moderate CVD risk
  - 10% to < 20%: moderate to high CVD risk
  - ≥ 20%: high CVD risk

Appendix K: Systematic Coronary Risk Evaluation (SCORE) Score[15, 16]

- The European Society of Cardiology (ESC) developed SCORE2 to estimate the 10-year fatal and non-fatal CVD risk in individuals without previous CVD or diabetes aged 40-69 years. The algorism assesses age, smoking status, systolic blood pressure, total cholesterols, and high-density lipoprotein cholesterol levels.
- ESC also developed SCORE2-Older Persons (SCORE2-OP) to estimate the 5- and 10-year risk of CVD in individuals aged above 70 years. The algorism considers age, smoking status, systolic blood pressure, diabetes, total cholesterols, and high-density lipoprotein cholesterol levels.
- The SCORE calculator can be found here: https://www.heartscore.org.

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Nexletol	180 mg PO QD	180 mg/day
Nexlizet	180 mg bempedoic acid and 10 mg of ezetimibe PO QD	180 mg bempedoic acid and 10 mg of ezetimibe /day

VI. Product Availability

Drug Name	Availability
Bempedoic acid (Nexletol)	Tablet: 180 mg
Bempedoic acid/ezetimibe (Nexlizet)	Tablet: bempedoic acid 180 mg/ezetimibe 10 mg

VII. References

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Guidelines

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	11.02.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	10.01.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.06.22	
1Q 2023 annual review: per 2022 ACC expert consensus decision pathway, lowered minimum LDL requirement to 55 mg/dL for members with ASCVD at very high risk and added corresponding Appendix I; references reviewed and updated.	10.18.22	02.23
Per guidelines: for HeFH, added pathway for baseline LDL of at least 160 mg/dL for age < 20 years.	05.17.23	08.23
1Q 2024 annual review: no significant changes; added the following requirement from initial approval criteria to also require for continuation of therapy "Treatment plan does not include coadministration with Repatha or Praluent;" Appendix I clarified that smoking is specific to tobacco and revised HeFH to FH; references reviewed and updated.	01.08.24	02.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
RT4: per updated prescribing information, revised indication to remove "maximally tolerated" wording from the description of statin therapy and removed limitation of use.		
RT4: criteria updated to reflect the revised indication for primary hyperlipidemia which now includes forms other than HeFH and the new indication for reducing the cardiovascular risk reduction in adults who are unable to take recommended statin therapy (including those not taking a statin) with established CVD or a high risk for a CVD event but without established CVD; reduced statin adherence duration from 4 months to 8 weeks, simplified statin trial and failure criteria for moderate- and low-intensity statin regimens to require insufficient therapeutic response to one high intensity statin for 8 weeks or reversible muscle-related symptoms associated with both rosuvastatin and atorvastatin; removed criteria restricting coadministration with Repatha or Praluent per PI.	04.11.24	
1Q 2025 annual review: in Appendix B, added pravastatin and fluvastatin as hydrophilic statin therapeutic alternatives; revised section V. Dosage and Administration to list Nexletol and Nexlizet dosing regimens separately; references reviewed and updated.	11.07.24	02.25

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.