Nexletol (bempedoic acid)
Nexlizet (bempedoic acid/ezetimibe)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Nexletol (bempedoic acid) and Nexlizet (bempedoic acid and ezetimibe) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Nexletol (bempedoic acid) is indicated:

- To reduce the risk of major cardiovascular events (cardiovascular death, myocardial infarction, stroke, or coronary revascularization) in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking a statin).
- As an adjunct to diet and exercise, 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 hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

Nexlizet (bempedoic acid and ezetimibe) is indicated:

- As an adjunct to diet and exercise to reduce LDL-C in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

Bempedoic acid, a component of Nexlizet is indicated:

- To reduce the risk of major cardiovascular events (cardiovascular death, myocardial infarction, stroke, or coronary revascularization) in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking a statin).

POLICY

Required Documentation

The following information is necessary to initiate the prior authorization review:

- Untreated baseline LDL-C level, LDL-C levels while receiving statin therapy (prior to starting Nexletol/Nexlizet therapy) and current LDL-C levels on Nexletol/Nexlizet (if applicable)
- Untreated baseline apolipoprotein B (apoB), apoB level while receiving statin therapy (prior to starting Nexletol/Nexlizet therapy)
- Chart notes demonstrating the member is engaging in healthy lifestyle changes (i.e. low-fat diet and exercise regimen)
- For prevention of ASCVD: documentation of ASCVD risk score using PREVENT-ASCVD equations, risk enhancers or another clinically appropriate risk score and/or calculator
- For statin intolerance: Chart notes demonstrating statin intolerance or contraindication to statin therapy
- For heterozygous familial hypercholesterolemia: Lab results (i.e. pathogenic variant in the LDL-receptor [LDLR], apolipoprotein B [APOB], proprotein convertase subtilisin/Kexin type 9 [PCSK9], or LDL-receptor adaptor protein 1 [LDLRAP1]) or rating scale (i.e. Simon-Broome Diagnostic Criteria, Dutch Lipid Network Criteria, or Make Early Diagnosis to Prevent Early Death Criteria)

Criteria for Initial Approval

A. **Nexletol** (bempedoic acid) and **Nexlizet** (bempedoic acid and ezetimibe) may be considered **medically necessary** for the **treatment of clinical atherosclerotic cardiovascular disease (ASCVD)** or for the **prevention of ASCVD** for members at high risk when all of the following criteria are met:

1. Member is 18 years of age or older
2. Member has a history of one of the following:
    a. Clinical ASCVD (Appendix A)
    b. High-risk for ASCVD with one of the following:
        - PREVENT-ASCVD equations calculate a 10-year ASCVD risk score ≥ 10%
        - PREVENT-ASCVD equations calculate an intermediate 10-year ASCVD risk score of 5% to <10% and the presence of one or more ASCVD risk enhancers (Appendix B)
        - PREVENT-ASCVD 10-year ASCVD risk score is expected to underestimate the member's risk for ASCVD and an alternative risk score (i.e., MESA, Qrisk3) calculates a 10-year risk score ≥ 10%
        - Member has diabetes and is at higher cardiovascular risk
3. Member is engaging in healthy lifestyle changes
4. Member has one of the following laboratory values despite adherence to the combination of lifestyle changes and at least three months of maximally tolerated high-intensity statin therapy:
    a. A low-density lipoprotein-cholesterol (LDL-C) ≥ 70 mg/dL
    b. An LDL-C ≥ 55 mg/dL with history of multiple clinical atherosclerotic cardiovascular disease [ASCVD] events or one major ASCVD event and multiple high-risk conditions (Appendix C)
    c. An apolipoprotein B ≥ 80 mg/dL

5. Nexletol will be added to statin and ezetimibe therapy or Nexlizet will be added to statin therapy

OR

1. Member is 18 years of age or older
2. Member has a history of one of the following:
   a. Clinical ASCVD (Appendix A)
   b. High-risk for ASCVD with one of the following:
      - PREVENT-ASCVD equations calculate a 10-year ASCVD risk score ≥ 10%
      - PREVENT-ASCVD equations calculate an intermediate 10-year ASCVD PCE score of 5% to <10% and the presence of one or more ASCVD risk enhancers (Appendix B)
      - PREVENT-ASCVD 10-year risk score is expected to underestimate the member's risk for ASCVD and an alternative risk score (i.e., MESA, Qrisk3) calculates a 10-year risk score ≥ 10%
      - Member has diabetes and is at higher cardiovascular risk
3. Member is engaging in healthy lifestyle changes
4. Member has one of the following laboratory values:
   a. A current LDL-C level ≥ 70 mg/dL
   b. A current LDL-C level ≥ 55 mg/dL with history of multiple clinical atherosclerotic cardiovascular disease (ASCVD) events or one major ASCVD event and multiple high-risk conditions (See Appendix C)
   c. An apolipoprotein B ≥ 80 mg/dL
5. Member has a documented contraindication (e.g., active liver disease, pregnancy, breastfeeding), or medically justifiable reason that precludes statin use (e.g. member has experienced rhabdomyolysis, CK elevations ≥ 10x ULN, or statin intolerance defined in accordance with the National Lipid Association definition [Appendix D]).

Approval will be for **12 months**

B. Nexletol (bempedoic acid) and **Nexlizet** (bempedoic acid and ezetimibe) may be considered **medically necessary** for the treatment of **heterozygous familial hypercholesterolemia (HeFH)** when the following criteria are met:
1. Member is 18 years of age or older
2. Member has a definite diagnosis of HeFH, which is confirmed by ONE of the following:
   a). A pathogenic variant in the LDL-receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin/Kexin type 9 (PCSK9), or LDL-receptor adaptor protein 1 (LDLRAP1); **OR**
   b). Definite FH per Simon-Broome Diagnostic Criteria, Dutch Lipid Network Criteria (Appendix E), or Definite FH per US Make Early Diagnosis to Prevent Early Death (MEDPED) Diagnostic Criteria
3. Member is engaging in healthy lifestyle changes
4. Member has been unable to achieve an LDL-C of < 70 mg/dL (or < 55 mg/dL with history of multiple clinical atherosclerotic cardiovascular disease [ASCVD] events or one major ASCVD event and multiple high-risk conditions [See Appendix C]) despite adherence to the combination of lifestyle changes and at least three months of BOTH the following lipid lowering therapies:
   a. Maximally tolerated high-intensity statin therapy
   b. PCSK9-targeted therapy
5. Nexletol will be added to statin and ezetimibe therapy or Nexlizet will be added to statin therapy

OR

1. Member is 18 years of age or older
2. Member has a definite diagnosis of HeFH, which is confirmed by ONE of the following:
   a). A pathogenic variant in the LDL-receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin/Kexin type 9 (PCSK9), or LDL-receptor adaptor protein 1 (LDLRAP1); **OR**
   b). Definite FH per Simon-Broome Diagnostic Criteria, Dutch Lipid Network Criteria (Appendix E), or definite FH per US Make Early Diagnosis to Prevent Early Death (MEDPED) Diagnostic Criteria
3. Member is engaging in healthy lifestyle changes
4. Member has been unable to achieve an LDL-C of <70 mg/dL (or < 55 mg/dL with history of multiple clinical atherosclerotic cardiovascular disease [ASCVD] events or one major ASCVD event and multiple high-risk conditions [See Appendix C]) despite adherence to the combination of lifestyle changes and at least a three-month trial of PCSK9-targeted therapy
5. Member has a documented contraindication (e.g., active liver disease, pregnancy, breastfeeding), or medically justifiable reason that precludes statin use (e.g. member has experienced rhabdomyolysis, CK elevations ≥ 10x ULN, or statin intolerance defined in accordance with the National Lipid Association [Appendix D]).

Approval will be for **12 months**

C. Nexletol (bempedoic acid) and **Nexlizet** (bempedoic acid and ezetimibe) may be considered **medically necessary** for the treatment of **primary hyperlipidemia** when the following criteria is met:

1. Member is 18 years of age or older
2. Member has a diagnosis of primary hyperlipidemia in which both of the following criteria are met:
   a. Member had an untreated LDL-C level ≥ 160 mg/dL
   b. Member does not have a secondary cause of hyperlipidemia
3. Member is engaging in healthy lifestyle changes
4. Member has been unable to achieve a low-density lipoprotein-cholesterol (LDL-C) <70 mg/dL despite adherence to the combination of lifestyle changes and at least three months of maximally tolerated statin therapy.
5. Nexletol will be added to statin and ezetimibe therapy or Nexlizet will be added to statin therapy

OR

1. Member is 18 years of age or older
2. Member has a diagnosis of primary hyperlipidemia in which both of the following criteria are met:
   a. Member had an untreated LDL-C level ≥ 160 mg/dL
   b. Member does not have a secondary cause of hyperlipidemia
3. Member is engaging in healthy lifestyle changes
4. Member has a current LDL-C level ≥ 70 mg/dL
5. Member has a documented contraindication (e.g., active liver disease, pregnancy, breastfeeding), or medically justifiable reason that precludes statin use (e.g., member has experienced rhabdomyolysis, creatine kinase [CK] elevations ≥ 10x ULN, or statin intolerance defined in accordance with the National Lipid Association [Appendix D]).

Approval will be for **12 months**

Continuation of Therapy

The continuation of therapy for either Nexletol or Nexlizet may be considered **medically necessary** for the treatment of any indication listed in the Criteria for Initial Approval when all the following criteria are met:

1. Member has experienced a reduction in LDL-C or has maintained a reduction in LDL-C
2. Member continues to receive concomitant maximally tolerated LDL-C lowering therapy (unless contraindicated or not tolerated)
3. Member continues to demonstrate adherence with Nexletol or Nexlizet, any concomitant LDL-C lowering therapies (if applicable), and lifestyle modifications

Approval will be for **12 months**

The aforementioned drugs are considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

- Nexletol 180 mg –30 tablets per 30 days
- Nexlizet 180mg/10mg – 30 tablets per 30 days

APPENDIX

APPENDIX A: Clinical Atherosclerotic Cardiovascular Disease (ASCVD)

- Acute coronary syndromes
- Myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization procedure (e.g., percutaneous coronary intervention [PCI], coronary artery bypass graft [CABG] surgery)
- Stroke of presumed atherosclerotic origin
- Transient ischemic attack (TIA)
- Lower-extremity peripheral arterial disease (PAD) or other atherosclerotic forms of PAD including aortic aneurysm
- Obstructive coronary artery disease (defined as fifty percent or greater stenosis on cardiac computed tomography angiogram or catheterization)
- Coronary Artery Calcium (CAC) Score ≥300

APPENDIX B: ASCVD Risk Enhancers

- Family history of premature ASCVD in a parent or sibling (males, age <55 years; females, age <65 years)

- Higher risk ancestry (e.g., South Asian, Filipino)
- High polygenic risk (if measured)
- Chronic inflammatory diseases (e.g., systemic lupus, RA, advanced psoriasis, inflammatory arthritis)
- Lp(a) ≥125 nmol/L or ≥50 mg/dL
- hs-CRP ≥2.0 mg/L on > 1 occasion (if measured)
- TG persistently ≥175 mg/dL (2 mmol/L) (if nonfasting) and ≥150 mg/dL (1.7 mmol/L) (if fasting)
- CKM syndrome
- LDL-C persistently ≥160-189 mg/dL (4.1-4.9 mmol/L), non-HDL-C ≥190-219 mg/dL or apoB ≥120 mg/dL
- Reproductive risk markers (premature menopause, preeclampsia, gestational diabetes, gestational hypertension, preterm delivery)

APPENDIX C: Criteria for Identifying Patients with ASCVD at Very High Risk* of Future ASCVD Events

Major ASCVD Events	Acute coronary syndrome within the past 12 months
	History of myocardial infarction
	History of ischemic stroke
	Symptomatic PAD (claudication with ABI <0.85 or previous revascularization of amputation)
High-Risk Conditions	Age ≥ 65 years
	History of prior coronary artery bypass surgery or PCI outside of the major ASCVD event(s)
	Diabetes
	Hypertension
	Current smoker
	Persistently elevated LDL-C (≥100 mg/dL [≥2.6 mmol/L]) despite maximally tolerated statin therapy and ezetimibe
	History of congestive HF

*Very high risk includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions.

APPENDIX D: Statin intolerance defined in accordance with the National Lipid Association definition

Inability to tolerate at least two statins (one at any dose, one at lowest daily dose) due to objectionable symptoms or abnormal biomarkers temporally related to statin use, reversible upon statin discontinuation and reproducible by re-challenge while excluding other known determinants. Other known determinants include low body mass index (BMI), acute infection, untreated or undertreated hypothyroidism, severe renal or hepatic dysfunction, organ transplant, recent severe trauma, HIV infection, Vitamin D deficiency, history of CK elevation, history of preexisting or unexplained muscle or joint pain, high level of physical activity, illicit drug abuse, excess alcohol use. Each statin trial, both initial and re-challenge shall be at least two weeks duration.

- A trial of one statin at lowest starting daily dose
  - Rosuvastatin 5mg
  - Atorvastatin 10mg
  - Simvastatin 10mg
  - Lovastatin 20mg
  - Pravastatin 40mg
  - Fluvastatin 40mg
  - Pitavastatin 2mg
- One statin at any daily dose

APPENDIX D: Diagnosis of definite familial hypercholesterolemia (FH)

1. Simon-Broome Diagnostic Criteria for definite FH
   a) Total cholesterol > 290 mg/dL or LDL-C > 190 mg/dL in patients over 16 years of age or total cholesterol > 260 mg/dL or LDL-C > 155 mg/dL in patients less than 16 years of age
   AND
   b) Tendon xanthomas in the patient, first (parent, sibling or child) or second degree relative (grandparent, uncle or aunt)
2. Dutch Lipid Clinic Network Criteria for definite FH
   a) Total score > 8 points

CLINICAL RATIONALE

Nexletol is an adenosine triphosphate-citrate lyase (ACL) inhibitor that inhibits cholesterol synthesis in the liver and thereby lowers LDL-C. ACL is an enzyme upstream of 3-hydrox-3-methyl-glutaryl-coenzyme A (HMG-CoA) reductase in the cholesterol synthesis pathway. Inhibiting ACL results in decreased cholesterol synthesis in the liver and lowers LDL-C in blood via upregulation of low-density lipoprotein receptors.

Efficacy

The efficacy and safety of bempedoic acid was assessed in four phase III trials: CLEAR Harmony, CLEAR Wisdom, CLEAR Serenity, and CLEAR Tranquility. CLEAR Harmony and CLEAR Wisdom were both phase III, multi-center, randomized, double-blind, placebo-controlled 52 week trials that enrolled adult patients with heterozygous familial hypercholesterolemia and/or established atherosclerotic cardiovascular disease whose LDL levels were not adequately controlled on maximally tolerated statin therapy.

In CLEAR Harmony, the overall mean age at baseline was 66 years (range: 24 to 88 years). 95% of patients had established atherosclerotic cardiovascular disease, and 5% of patients had HeFH. The mean baseline LDL-C was 103.2 mg/dL. Patients were followed for 52 weeks with lipid panels done at week 4, 8, 12, 24, 36 and 52. The primary efficacy outcome measure of the study was the percent change from baseline to Week 12 in LDL-C. The difference between Nexletol and placebo in mean percent change in LDL-C from baseline to Week 12 was -18% (95% CI: -20%, -16%; $p < 0.001$). High-density lipoprotein (HDL) and triglycerides (TG) were examined as exploratory endpoints and were not included in the statistical hierarchy. The difference between Nexletol and placebo in mean percent change from baseline to Week 12 was -6% for HDL and median percent change from baseline to Week 12 was +3% for TG.

In CLEAR Wisdom, the overall mean age at baseline was 64 years (range: 28 to 91 years). 95% of patients had established atherosclerotic cardiovascular disease, and 5% of patients had HeFH. The mean baseline LDL-C was 120.4 mg/dL. Patients were followed for 52 weeks with lipid panels done at week 4, 12, 24, and 52. The primary efficacy outcome measure of the study was the percent change from baseline to Week 12 in LDL-C. The difference between NEXLETOL and placebo in mean percent change in LDL-C from baseline to Week 12 was -17 % (95% CI: -21%, -14%; $p < 0.001$). HDL and TG were exploratory endpoints and not included in the statistical hierarchy. The difference between Nexletol and placebo in mean percent change from baseline to Week 12 was -6% for HDL and the median percent change from baseline was -2% for TG.

CLEAR Serenity was a phase III, double-blind, placebo-controlled study that randomized 345 patients with hypercholesterolemia and a history of intolerance to at least 2 statins (1 at the lowest available dose) that still required additional lipid-lowering for primary or secondary prevention of CV events. Patients were randomized 2:1 to bempedoic acid 180 mg or placebo once daily for 24 weeks. The primary end point was mean percent change from baseline to week 12 in low-density lipoprotein cholesterol. The mean age was 65.2 years, mean baseline low-density lipoprotein cholesterol was 157.6 mg/dL, and 93% of patients reported a history of statin-associated muscle symptoms. Nexletol treatment significantly reduced low-density lipoprotein cholesterol from baseline to week 12 (placebo-corrected difference, -21.4% [95% CI, -

25.1% to -17.7%]; P<0.001). Significant reductions with Nexletol versus placebo were also observed in non-high-density lipoprotein cholesterol (-17.9%), total cholesterol (-14.8%), apolipoprotein B (-15.0%), and high-sensitivity C-reactive protein (-24.3%; P<0.001 for all comparisons).

CLEAR Tranquility was a phase III, multinational, randomized, double-blind, placebo-controlled, 12 week trial that studied the combination of Nexletol (bempedoic acid) and Zetia (ezetimibe) in patients with a history of statin intolerance and an LDL-C ≥ 100 mg/dL while receiving stable lipid-lowering therapy. In general, the study population demographics were similar to the Nexletol trials; the mean baseline LDL-C level was 129.8 mg/dL for the Nexletol arm. During the run-in phase, all patients received open-label Zetia to confirm tolerance to Zetia. At the double-blind treatment phase, patients were randomized to receive Nexletol or placebo for 12 weeks while the open-label Zetia treatment was maintained throughout the study. The addition of Nexletol to Zetia achieved a placebo-adjusted reduction in LDL-C of 28.5% (95% confidence interval -34.4 to -22.5; p < 0.001) to a mean LDL-C level of 96.2 mg/dL at 12 weeks. Significant reductions in secondary endpoints, including non-high-density lipoprotein cholesterol (-23.6%), total cholesterol (-18.0%), apolipoprotein B (-19.3%), and high-sensitivity C-reactive protein (-31.0%) , were observed with Nexletol vs. placebo (p < 0.001).

CLEAR Outcomes was a phase III, event-driven, multicenter, randomized, double-blind, placebo-controlled trial that studied the effect on Nexletol (bempedoic acid) on four-component composite of major adverse cardiovascular events (MACE-4) in patients who were statin-intolerant and qualified for primary or secondary prevention of cardiovascular disease. Nearly 14,000 patients underwent randomization and were permitted to continue stable doses of other lipid-lowering therapies. A pre-defined 30% of participants received Nexletol for primary prevention while the remaining 70% were treated for secondary prevention. The mean baseline LDL-C was 139.0 mg/dL in both groups. The primary end-point event was significantly lower with bempedoic acid (11.7%) as compared to placebo (13.3%) for a 13% risk reduction (HR 0.87; 95% CI 0.79-0.96; p=0.004) over a median follow-up period of 40.6 months. Statistically significant secondary outcomes favoring bempedoic acid over placebo were observed for MACE-3, risk of myocardial infarction, and risk of coronary revascularization. However, no significant effects were noted on fatal or nonfatal stroke, death from cardiovascular causes, and death from any cause.

Safety

In clinical trials, the most common reasons for Nexletol treatment discontinuation were muscle spasms (0.5% vs 0.3% placebo), diarrhea (0.4% vs 0.1% placebo), and pain in extremity (0.3% vs 0% placebo). The most common adverse reactions (incidence ≥ 2% and greater than placebo) were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes. Nexletol was associated with an increased risk of tendon rupture and gout. Concomitant use of Nexletol with simvastatin at a dose greater than 20 mg or pravastatin at a dose greater than 40 mg should be avoided due to an increased risk of statin-related myopathy. Nexlizet safety outcomes were similar to findings from the Nexletol trials.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD-CM diagnostic codes.

- N/A

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POLICY HISTORY

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