

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2023 P 2212-4
Program	Prior Authorization/Medical Necessity
Medication	Nexletol® (bempedoic acid), Nexlizet® (bempedoic acid/ezetimibe)
P&T Approval Date	7/2020, 8/2021, 9/2022, 11/2023
Effective Date	2/1/2024

**1. Background:**

Nexletol (bempedoic acid) and Nexlizet (bempedoic acid/ezetimibe) are indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

The effect of Nexletol and Nexlizet on cardiovascular morbidity and mortality has not been determined.

**2. Coverage Criteria<sup>a</sup>:**

**A. Hyperlipidemia**

**1. Initial Authorization**

a. **Nexletol** and **Nexlizet** will be approved based on **all** the following criteria:

(1) **One** of the following diagnoses:

- (a) Heterozygous familial hypercholesterolemia (HeFH)
- (b) Atherosclerotic cardiovascular disease (ASCVD)

**-AND-**

(2) **One** of the following:

- (a) Patient has been receiving at least 12 consecutive weeks of **high intensity statin\* therapy** [i.e. atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a high intensity statin at maximally tolerated dose

**-OR-**

(b) **Both** of the following:

- i. Patient is unable to tolerate high-intensity statin as evidenced by **one** of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:
  - 1. Myalgia (muscle symptoms without CK elevations)
  - 2. Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN])

-AND-

- ii. Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin\* therapy [i.e. atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin  $\geq$  10 mg, pravastatin  $\geq$  10 mg, lovastatin 20-40 mg, fluvastatin extended-release 80 mg, fluvastatin 20-40 mg up to 40mg twice daily or Livalo (pitavastatin)  $\geq$  1 mg] and will continue to receive a low-intensity or moderate-intensity statin at maximally tolerated dose

-OR-

- (c) Patient is unable to tolerate **low or moderate-, and high-intensity statins** as evidenced by **one** of the following:

- i. **One** of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate-, and high-intensity statins:
  1. Myalgia (muscle symptoms without CK elevations)
  2. Myositis (muscle symptoms with CK elevations  $<$  10 times upper limit of normal [ULN])

-OR-

- ii. Patient has a labeled contraindication to all statins as documented in medical records

-OR-

- iii. Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations  $>$  10 times ULN

-AND-

- (3) **One** of the following:

- (a) Documentation of **one** of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:
  - i. LDL-C  $\geq$  100 mg/dL with ASCVD
  - ii. LDL-C  $\geq$  130 mg/dL without ASCVD

-OR-

- (b) **Both** of the following:

i. Documentation of **one** of the following LDL-C values while on maximally tolerated lipid lowering therapy for a minimum of at least 12 weeks within the last 120 days:

1. LDL-C between 70 mg/dL and 99 mg/dL with ASCVD
2. LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

**-AND-**

ii. Documentation of **one** of the following:

1. Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia®) therapy as adjunct to maximally tolerated statin therapy

**-OR-**

2. Patient has a history of contraindication, or intolerance to ezetimibe

**Authorization will be issued for 12 months**

## 2. **Reauthorization**

a. **Nexletol** and **Nexlizet** will be approved based on **both** the following:

- (1) Documentation of a positive clinical response to therapy

**-AND-**

- (2) Patient continues to receive statin\* at maximally tolerated dose (unless patient has documented inability to take statins)

**Authorization will be issued for 12 months**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

\*Tried/failed alternatives are supported by FDA labeling.

## 3. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place

## 4. **References:**

1. Nexletol [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc; June 2023.
2. Nexlizet [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc; June 2023.

3. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2014;63:2889-934.
4. The Lipid Research Clinics Coronary Primary Prevention Trial results. II. The relationship of reduction in incidence of coronary heart disease to cholesterol lowering. *JAMA.* 1984;251:365-74.
5. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American association of clinical endocrinologists and American college of endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease. *Endocr Pract.* 2017; Suppl 2;23:1-87.
6. Lloyd-Jones D, Morris P, Ballantyne C, et al. 2017 Focused update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk. *J Am Coll Cardiol.* 2017.
7. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation.* 2018; DOI: 10.1161/CIR.0000000000000625.

Program	Prior Authorization/Medical Necessity – Nexletol and Nexlizet
<b>Change Control</b>	
7/2020	New program.
8/2021	Annual review. Updated references.
9/2022	Annual review. Condensed low intensity and moderate-intensity statin therapy sections. Added footnote that statin requirement is supported by FDA labeling. Updated references.
11/2023	Annual review. Updated background and references.