UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2212-6
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, 6/2024, 8/2025
Effective Date	11/1/2025

1. Background:

Nexletol (bempedoic acid) and Nexlizet (bempedoic acid/ezetimibe) are indicated as an adjunct to diet and tother 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), and 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

2. Coverage Criteria[a]:

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) Primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH)

(b) Established cardiovascular disease (CVD) as documented by **one** of the following:

(i) coronary artery disease
(ii) symptomatic peripheral arterial disease
(iii) cerebrovascular atherosclerotic disease

(c) High risk for cardiovascular disease (CVD) as documented by one of the following:

(i) diabetes and over 60 years old
(ii) Reynolds risk score greater than 30%
(iii) coronary artery calcium score greater than 400 Agatston units
(iv) ASCVD risk score greater than or equal to 20% with the American College of Cardiology/American Heart Association (ACC/AHA) risk estimator

-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 ≥ 10 mg, pravastatin ≥ 10 mg, lovastatin 20-40 mg, fluvastatin extended-release 80 mg, fluvastatin 20-40 mg up to 40mg twice daily or Livalo (pitavastatin) ≥ 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 ≥ 100 mg/dL with ASCVD

ii. LDL-C ≥ 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 55 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

[a] 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; March 2024.
2. Nexlizet [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc; March 2024.
3. 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.
4. 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.
5. Writing Committee, Lloyd-Jones DM, Morris PB, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2022;80(14):1366-1418. doi:10.1016/j.jacc.2022.07.006
6. ASCVD Risk Estimator. American College of Cardiology/American Heart Association joint publication. 2014. Assessed July 1, 2025. https://tools.acc.org/ascvd-risk-estimator/default.aspx.
7. Patel, S. B., Wyne, K. L., Afreen, S., Pulipati, V. P., Sultan, S., Zilbermint, M., et al. (2025). American Association of Clinical Endocrinology clinical practice guideline on pharmacologic management of adults with dyslipidemia. American Association of Clinical Endocrinology. https://pro.aace.com/clinical-guidance/2025-clinical-practice-guideline-pharmacologic-management-adults-dyslipidemia[1](https://pro.aace.com/clinical-guidance/2025-clinical-practice-guideline-pharmacologic-management-adults-dyslipidemia)

Program	Prior Authorization/Medical Necessity – Nexletol and Nexlizet
Change Control	
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.
6/2024	Updated indications to include established and high risk for CVD based on updated labeling. Lowered LDL-C threshold for initiation of therapy.

8/2025	Annual review. Updated references.