UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3146-5
Program	Step Therapy
Medications	Nexletol® (bempedoic acid), Nexlizet® (bempedoic acid/ezetimibe)
P&T Approval Date	8/2020, 8/2021, 9/2022, 11/2023, 11/2024
Effective Date	2/1/2025

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to have a trial of a maximally tolerated statin therapy and ezetimibe prior to coverage for Nexletol or Nexlizet.

2. Coverage Criteria[a]:

A. Authorization

1. **Nexletol or Nexlizet** will be approved based on **both** of the following criteria:

   a. **One** of the following:

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

      -OR-

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

         (a) 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:
         - Myalgia (muscle symptoms without CK elevations)
         - Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN])

         -AND-

         (b) 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-

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

(a) One of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:
- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN])

-OR-

(b) Patient has a labeled contraindication to all statins

-OR-

(c) Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN

-AND-

b. 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.

[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.
- Medical Necessity and/or 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. 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	Step Therapy- Nexletol (bempedoic acid), Nexlizet (bempedoic acid/ezetimibe)
Change Control	
8/2020	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 references.
11/2024	Annual review. Updated references.