PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

NEXLETOL
(bempedoic acid)

NEXLIZET
(bempedoic acid/ezetimibe)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Nexletol

Nexletol is indicated:

- 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
- 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).

Nexlizet

Nexlizet, a combination of bempedoic acid and ezetimibe, is indicated:

- As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

The bempedoic acid component of Nexlizet is indicated:

- 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

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed to reduce low-density lipoprotein cholesterol (LDL-C) in an adult with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH)
  AND
  - The requested drug is being prescribed as an adjunct to diet
    AND
    - The request is NOT for continuation of therapy
      AND
      - The requested drug will be used in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies

      OR

- Concomitant use of the requested drug with other low-density lipoprotein cholesterol (LDL-C) lowering therapies is not possible

OR

- The request is for continuation of therapy

  AND

  - The patient has achieved or maintained a reduction in low-density lipoprotein cholesterol (LDL-C) from baseline

OR

- The requested drug is being prescribed to reduce the risk of myocardial infarction and coronary revascularization in an adult

  AND

  - The patient has ANY of the following: A) established cardiovascular disease (CVD), B) a high risk for a cardiovascular disease (CVD) event but without established CVD

    AND

    - The patient experienced an intolerance to the recommended statin therapy

    OR

    - The patient has a contraindication that would prohibit use of statin therapy

Duration of Approval (DOA):

- 3647-A: DOA: 36 months

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. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed October 10, 2023.
4. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 10/10/2023).
5. 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. *Circulation* 2019;139:e1082-1143.
6. Hadelsman, et. al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Management of Dyslipidemia and Prevention of Cardiovascular Disease Algorithm - 2020 Executive Summary. Endocr Pract. 2020;26(No. 10)
7. Lloyd-Jones DM, Morris PB, Ballantyne CM, 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;80:1366-1418.