



# Initial Prior Authorization

## Nexletol, Nexlizet

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Nexletol	bempedoic acid
Nexlizet	bempedoic acid/ezetimibe

### Indications

#### FDA-approved Indications

##### Nexletol

Nexletol is indicated:

- To reduce the risk of major adverse 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

Nexlizet, a combination of 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).

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Bempedoic acid, a component of Nexlizet, is indicated:

- To reduce the risk of major adverse 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).

## Coverage Criteria

### Hypercholesterolemia, including Heterozygous Familial Hypercholesterolemia (HeFH)

Authorization may be granted when the requested drug is being prescribed to reduce low-density lipoprotein cholesterol (LDL-C) in an adult with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH) when ALL of the following criteria are met:

- The requested drug is being prescribed as an adjunct to diet and exercise.
- If the request is for Nexletol, the patient meets ONE of the following:
  - The requested drug will be used in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies.
  - Concomitant use of the requested drug with other low-density lipoprotein cholesterol (LDL-C) lowering therapies is NOT possible.

### Risk Reduction of Major Adverse Cardiovascular Events

Authorization may be granted when the requested drug is being prescribed to reduce the risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, stroke, or coronary revascularization) in an adult at increased risk for these events when the following criteria is met:

- The patient meets ONE of the following:
  - The patient experienced an intolerance to the recommended statin therapy.
  - The patient has a contraindication that would prohibit use of statin therapy.

# Continuation of Therapy

## Hypercholesterolemia, including Heterozygous Familial Hypercholesterolemia (HeFH)

Authorization may be granted when the requested drug is being prescribed to reduce low-density lipoprotein cholesterol (LDL-C) in an adult with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH) when ALL of the following criteria are met:

- The requested drug is being prescribed as an adjunct to diet and exercise.
- The patient has achieved or maintained a reduction in low-density lipoprotein cholesterol (LDL-C) from baseline.

## Risk Reduction of Major Adverse Cardiovascular Events

All patients (including new patients) requesting authorization for continuation of therapy must meet ALL requirements in the coverage criteria section.

## Duration of Approval (DOA)

- 3647-A: DOA: 36 months

## References

1. Nexletol [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc; November 2025.
2. Nexlizet [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc; November 2025.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 24, 2024.
4. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed October 24, 2024.
5. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 10/24/2024).
6. 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* 2019 Jun 18;139(25):e1082-1143.
7. Hadelsman Y, Jellinger PS, Guerin CK, et. al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Management of Dyslipidemia

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and Prevention of Cardiovascular Disease Algorithm -2020 Executive Summary. *Endocr Pract.* 2020;26(10):1196-1224.

8. 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.