

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 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:

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- 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

Primary Hyperlipidemia, 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 primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH) when ALL of the following criteria are met:

- The requested drug is being prescribed as an adjunct to diet.
- 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 Myocardial Infarction and Coronary Revascularization

Authorization may be granted when the requested drug is being prescribed to reduce the risk of myocardial infarction and coronary revascularization in an adult when ALL of the following criteria are met:

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

Primary Hyperlipidemia, 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 primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH) when ALL of the following criteria are met:

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

Risk Reduction of Myocardial Infarction and Coronary Revascularization

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; 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.; 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.