AETNA BET	TER HEALTH®		*ae	etna [™]		
Coverage Policy/Guideline						
Name:	Nexletol		Page:	1 of 2		
Effective Date: 8/1/2024			Last Review Date:	6/3/2024		
Applies to:	□Illinois	⊠New Jersey	⊠Florida Kids			
	⊠Pennsylvania Kids	⊠Virginia	⊠Maryland			

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Nexletol under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

- 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:
 - o established cardiovascular disease (CVD), OR
 - o 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).

Applicable Drug List:

Nexletol

Policy/Guideline:

Criteria for Initial Approval:

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 lowdensity 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

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 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), or 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

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 months

Quantity Level Limit: 30 tablets per 30 days

References:

- 1. Nexletol [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc; March 2024.
- 2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. https://online.lexi.com. Accessed October 10, 2023.
- 3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/<u>(cited: 10</u>/10/2023).
- 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. *Circulation* 2019;139:e1082-1143.
- 5. 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)
- 6. 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.