Commercial & Healthcare Exchange PA Criteria

Effective: June 3, 2020

Prior Authorization: Nexletol & Nexlizet

Products Affected: Nexletol (bempedoic acid) oral tablets, Nexlizet (bempedoic acid and ezetimibe) oral tablets

Medication Description: Bempedoic acid is an adenosine triphosphate-citrate lyase (ACL) inhibitor that lowers low-density lipoprotein cholesterol (LDL-C) through inhibition of cholesterol synthesis in the liver.

Ezetimibe nhibits absorption of cholesterol at the brush border of the small intestine via the sterol transporter, Niemann-Pick C1-Like1 (NPC1L1). This leads to a decreased delivery of cholesterol to the liver, reduction of hepatic cholesterol stores and an increased clearance of cholesterol from the blood; decreases total C, LDL-cholesterol (LDL-C), ApoB, and triglycerides (TG) while increasing HDL-cholesterol (HDL-C).

Covered Uses: Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

Exclusion Criteria: Nexlizet: Hypersensitivity to ezetimibe

Required Medical Information:

1. Diagnosis
2. Current LDL-C (within the past 90 days)
3. Previous therapies tried/failed

Age Restrictions: 18 years and older

Prescriber Restrictions: Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders

Coverage Duration: 12 months

Other Criteria:

1. Heterozygous Familial Hypercholesterolemia [HeFH].

Approve if the patient meets the following criteria (A, B, and C):

A) The patient meets the following criteria (i and ii):

- **i.** The patient has a current low-density lipoprotein cholesterol (LDL-C) level ≥ 100 mg/dL within the past 90 days; **AND**
- **ii.** The patient's diagnosis of HeFH is defined by WHO/Dutch Lipid group criteria **OR** Simon-Broome Criteria **OR** genetic testing; **AND**

B) The patient meets one of the following criteria (i or ii):

- **i.** The patient has tried at least ONE (1) high-intensity statin therapy (i.e., atorvastatin 80 mg daily or rosuvastatin 40 mg daily) for 8-12 continuous weeks [documentation required]; **AND** the LDL-C level remains ≥ 100 mg/dL [documentation required]; **OR**
- **ii.** The patient has been determined to be statin intolerant by meeting one of the following criteria (a or b):

a) The patient experienced statin-related rhabdomyolysis (statin-induced muscle breakdown with signs and symptoms such as muscle pain, weakness, tenderness, acute renal failure and/or elevated creatine kinase [CK] levels [e.g., greater or equal to 10 times the upper limit of normal]) [documentation required]; **OR**

b) The patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and meets both of the following criteria [(1) and (2)]:

(1) The skeletal-related muscle symptoms (e.g., myopathy or myalgia) occurred while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) [documentation required]; **AND**

(2) When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms (e.g., myopathy, myalgia) resolved upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin); **AND**

C) If able to tolerate statins, the patient continues to receive the maximum tolerated dose of a statin while receiving Nexletol or Nexlizet therapy.

2. Hyperlipidemia in Patients with Clinical Atherosclerotic Cardiovascular Disease (ASCVD).

Approve if the patient meets the following criteria (A, B, and C):

A) The patient meets the following criteria (i and ii):

i. The patient has a current low-density lipoprotein cholesterol (LDL-C) level ≥ 70 mg/dL within the past 90 days [documentation required]; **AND**

ii. The patient has had one of the following conditions or diagnoses (a, b, c, d, or e):

a) The patient has had a previous myocardial infarction (MI) or has a history of an acute coronary syndrome (ACS) [documentation required]; **OR**

b) The patient has a diagnosis of angina (stable or unstable) [documentation required]; **OR**

c) The patient has a past history of stroke or transient ischemic attack (TIA) [documentation required]; **OR**

d) The patient has peripheral arterial disease (PAD) [documentation required]; **OR**

e) The patient has undergone a coronary or other arterial revascularization procedure in the past (e.g., coronary artery bypass graft [CABG], percutaneous coronary intervention [PCI], angioplasty, coronary stent procedure) [documentation required]; **AND**

B) The patient meets one of the following criteria (i or ii):

i. The patient has tried at least ONE (1) high-intensity statin therapy (i.e., atorvastatin 80 mg daily or rosuvastatin 40 mg daily) for 8-12 continuous weeks [documentation required]; **AND** the LDL-C level remains ≥ 70 mg/dL [documentation required]; **OR**

ii. The patient has been determined to be statin intolerant by meeting one of the following criteria (a or b):

a) The patient experienced statin-related rhabdomyolysis (statin-induced muscle breakdown with signs and symptoms such as muscle pain, weakness, tenderness, acute renal failure and/or elevated creatine kinase [CK] levels [e.g., greater or equal to 10 times the upper limit of normal]) [documentation required]; **OR**

b) The patient experienced skeletal-related muscle symptoms (e.g., myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]) and meets both of the following criteria [(1) and (2)]:

(1) The skeletal-related muscle symptoms (e.g., myopathy or myalgia) occurred while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) [documentation required]; **AND**

(2) When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms (e.g., myopathy, myalgia) resolved upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin); **AND**

C) If able to tolerate statins, the patient continues to receive the maximum tolerated dose of a statin while receiving Nexletol or Nexlizet therapy.

References:

1. Nexletol [package insert]. Ann Arbor, MI; Esperion Therapeutics, Inc.2020
2. Micromedex® Healthcare Series; Thomson Micromedex, Greenwood Village, Co. 2019.
3. Drug Trials Snapshots: NEXLETOL, https://www.fda.gov/drugs/resources-information-approved-drugs/drug-trials-snapshots-nexletol. Accessed on May 19,2020
4. FDA Approves Nexletol (bempedoic acid) to Lower LDL-Cholesterol, https://www.drugs.com/newdrugs/fda-approves-nexletol-bempedoic-acid-lower-ldl-cholesterol-5164.html . Accessed May 19,2020
5. Karr, Samantha. Epidemiology and Management of Hyperlipidemia. AJMC Supplement. 2017 June 21, https://www.ajmc.com/journals/supplement/2017/pcsk9-inhibitors-a-guide-for-managed-care/epidemiology-and-management-of-hyperlipidemia-article
6. Nexletol. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed May 19,2020.
7. Nexlizet (bempedoic acid and ezetimibe) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics Inc; February 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	6/3/2020
1	Update	Addition of Nexlizet	All	9/2/2020