ALASKA MEDICAID
Prior Authorization Criteria

Nexletol™, Nexlizet™ (bempedoic acid, bempedoic acid/ezetimibe)

FDA INDICATIONS AND USAGE[1,2]

Nexletol™ is an adenosine triphosphate-citrate lyase (ACL) inhibitor 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. Nexlizet™ contains the active ingredient bempedoic acid, in combination with ezetimibe, a cholesterol absorption inhibitor.

APPROVAL CRITERIA[1,2,3]

1. Patient is 18 years of age or older **AND**;
2. Patient has a documented and confirmed diagnosis Heterozygous Familial Hypercholesterolemia (HeFH) **OR**;
3. Patient has a history of clinical atherosclerotic cardiovascular disease (ASCVD) including one or more of the following:
    a. Angina (stable or unstable)
    b. Acute coronary syndrome or prior myocardial infarction
    c. Coronary artery disease
    d. History of stroke or transient ischemic attack
    e. Stroke
    f. Peripheral artery disease
    g. Coronary or other arterial revascularization
4. Is being prescribed by or in consultation with a cardiologist, endocrinologist, or a physician that specializes in the treatment of cardiovascular disease and/or lipid disorders **AND**;
5. The patient is on concomitant statin therapy at maximally tolerated dose or has a contraindication or intolerance to at least two different statin medications **AND**;
6. The patient has a documented reduction of LDL-C less than 50% from the baseline or patient has ASVCD and LDL-C is greater than 70mg/dL or no history of ASCVD and a LDL-C is greater than 100mg/dL.

DENIAL CRITERIA[1,2]

1. Failure to meet approval criteria **OR;**
2. Patient will be taking more than 20mg of simvastatin or 40 mg of pravastatin daily **OR;**
3. Patient is currently using a Pcsk9 inhibitor.

CAUTIONS[1,2]

- Hyperuricemia has occurred with use. Monitor serum uric acid levels as clinically indicated.
- Tendon rupture has occurred, discontinue at first sign of tendon rupture and avoid use in patients with previous tendon rupture,

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Re-authorization: up to 12 months

QUANTITY LIMIT

- 30 tablets

REFERENCES / FOOTNOTES:

1. Nexletol [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc.; February 2020.
2. Nexlizet [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc.; February 2020.
3. Ray KK, Bays HE, Catapano AL, Lalwani ND, Bloedon LT, Sterling LR, et al. Safety and efficacy of bempedoic acid to reduce LDL cholesterol. N Engl J Med. 2019;380(11):1022–32.