blue of california

NEXLETOL (bempedoic acid, oral)
NEXLIZET (bempedoic acid/ ezetimibe, oral)

Diagnosis Considered for Coverage:

- Heterozygous familial hypercholesterolemia (HeFH)
- Established atherosclerotic cardiovascular disease
- Hypercholesterolemia/hyperlipidemia

Coverage Criteria:

For diagnosis above:

- Patient's age is consistent with FDA approved indication, **and**
- Dose does not exceed FDA approved maximum, **and**
- Inadequate response or intolerable side effect to ONE of the following, or contraindication to ALL of the following drugs:
    - Praluent (alirocumab)
    - Repatha (evolocumab)
    - Zetia (ezetimibe)
- One of the following (a or b):
    - **a) For use in combination with a high-intensity statin regimen:**
        - Current LDL cholesterol (LDL-C) is > 70 mg/dl (or > 55 mg/dl if provider states extreme risk for heart disease) despite 8 weeks of treatment

    OR

    b) For use WITHOUT a high-intensity statin in patients with documented statin intolerance:
        - Current LDL cholesterol (LDL-C) is > 70 mg/dl (or > 55 mg/dl if provider states extreme risk for heart disease), **and**
        - One of the following (a or b):
            a) Documentation that patient has an FDA approved package insert (PI) supported contraindication to treatment with all statins, **or**
            b) Patient has ALL of the following:
                - Intolerable muscle symptoms which are reversible upon statin discontinuation, but recur upon re-challenge with statin treatment, and
                - Other potential causes of intolerable muscle symptoms have been maximally managed or ruled out, and
                - Trial of at least two different statins (at least one statin is a high-intensity statin such as rosuvastatin

or atorvastatin at lowest starting dose), **and** • ***For Nexlizet only***: Patient is currently on ezetimibe (Zetia) or provider plans to add ezetimibe and request to reduce pill burden, **and**
Coverage Duration: one year

Effective Date: 01/03/2024