blue of california

REPATHA (evolocumab)

Diagnoses Considered for Coverage:

- Homozygous Familial Hypercholesterolemia (HoFH)
- Heterozygous Familial Hypercholesterolemia (HeFH)
- Hypercholesterolemia associated with clinical atherosclerotic cardiovascular disease (ASCVD)
- Reduction of the risk for myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease (aka prevention of CVD events)
- Primary hyperlipidemia, adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe)

Coverage Criteria:

1. **For all diagnoses above except HoFH:**
   - Dose does not exceed 140 mg SQ given every 2 weeks or 420 mg SQ given every 4 weeks, **and**
   - **For use in combination with a high-intensity statin regimen:**
     - Current LDL cholesterol (LDL-C) is > 70 mg/dl (or > 55 mg/dl if extreme risk for heart disease) despite 3 months of treatment with one of the following:
       - Ezetimibe (Zetia) used together with a high-intensity statin (atorvastatin 80 mg or Crestor 40 mg), **or**
       - Ezetimibe (Zetia) used together with atorvastatin (Lipitor) < 80 mg or Crestor < 40 mg for patients at increased risk for developing rhabdomyolysis, **or**
       - Maximally-tolerated high-intensity statin (atorvastatin 80 mg or Crestor 40 mg) for patients who require more LDL-C lowering than what can be expected from the addition of ezetimibe (Zetia)

   OR

   - **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**
     - Attestation that patient has an FDA approved package insert (PI) supported contraindication to treatment with all statins,

     OR

     - All of the following:
       - Attestation of intolerable muscle symptoms which are reversible upon statin discontinuation, but recur upon re-challenge with

statin treatment, and
- Attestation that 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 Crestor or atorvastatin at lowest starting dose), and
- Inadequate response to ezetimibe (Zetia) with another non-statin lipid-lowering drug regimen has not resulted in reduction in LDL to target goal, or patient requires more LDL-lowering than what can be expected with ezetimibe (Zetia) along with non-statin lipid-lowering drug regimen.

Coverage Duration: one year

2. **For Homozygous Familial Hypercholesterolemia (HoFH):**
   - Recommended by a cardiologist or endocrinologist, **and**
   - Confirmed homozygous familial hypercholesterolemia by EITHER positive genetic test for LDL-R genetic mutations confirming HoFH OR clinical evidence supporting a diagnosis of HoFH, **and**
   - Dose does not exceed 420 mg on-body infusor given every 2 weeks, **and**
   - Being used in combination with a standard lipid lowering combination regimen (e.g. a high potency statin and a non-statin lipid lowering agent)

   Coverage Duration: one year

Effective Date: 11/02/2023