blue of california

PRALUENT (alirocumab, SQ)

Diagnosis Considered for Coverage:

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

Coverage Criteria:

1. **For diagnoses above except HoFH:**

For use with a high-intensity statin:

1. **For Praluent:** Inadequate response, intolerable side effect, or contraindication to Repatha, **AND**
2. Current LDL cholesterol (LDL-C) is > 70 mg/dl (or > 55 mg/dl if extreme risk for heart disease) despite 8 weeks of treatment, **AND**
3. Dose does not exceed FDA approved maximum.

For use WITHOUT a high-intensity statin:

1. Patient has documented statin intolerance, **AND**
2. **For Praluent:** Inadequate response, intolerable side effect or contraindication to Repatha, **AND**
3. Current LDL cholesterol (LDL-C) is > 70 mg/dl (or > 55 mg/dl if provider states extreme risk for heart disease), **AND**
4. One of the following (a or b):
   a. Patient has an FDA approved package insert (PI) supported contraindication to treatment with all statins,
   OR
   b. All the following:
      1. Intolerable muscle symptoms which are reversible upon statin discontinuation, but recur upon re-challenge with statin treatment, **and**
      2. Other potential causes of intolerable muscle symptoms have been maximally managed or ruled out, **and**

3. 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

5. Dose does not exceed FDA approved maximum.

Coverage Duration: one year

1. **For Homozygous Familial Hypercholesterolemia (HoFH):**

1. Recommended by a cardiologist or endocrinologist
   AND
2. **For Praluent:** Inadequate response, intolerable side effect, or contraindication to Repatha
   AND
3. Confirmed homozygous familial hypercholesterolemia by EITHER:
   - positive genetic test for LDL-R genetic mutations confirming HoFH, or
   - clinical evidence supporting a diagnosis of HoFH
4. Being used in combination with a standard lipid lowering combination regimen (e.g. a high potency statin and a non-statin lipid lowering agent)

Statin Therapy atorvastatin (Lipitor) rosuvastatin (Crestor) simvastatin (Zocor) pitavastatin (Livalo)	**Fibrate Agents** Gemfibrozil (Lopid) Triglide (fenofibrate) Lipofen (fenofibrate) Fenoglide (fenofibrate) fenofibrate (Tricor, Lofibra) Antara (fenofibrate) Fenofibric (Fibricor) Trilipix (fenofibric)
Bile Acid Sequestrants colesevelam (Welchol) colestipol (Colestid) cholestyramine (Questran)	**Others** ezetimibe (Zetia) niacin (Niaspan)

AND

5. Dose does not exceed FDA maximum

Coverage Duration: one year

Coverage Duration: see above

Effective Date: 01/03/2024

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