ALASKA MEDICAID
Prior Authorization Criteria

Praluent® (alirocumab)
Repatha® (evolocumab)

FDA INDICATIONS AND USAGE[1]

Praluent is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor indicated:

- To reduce the risk of myocardial infarction, stroke and unstable angina requiring hospitalization in adults with established cardiovascular disease
- As adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C
- As an adjunct to other LDL-C-lowering therapies in adult patients with homozygous familial hypercholesteremia (HoFH) to reduce LDL-C.

Repatha is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor indicated:

- In adults with established cardiovascular disease (CVD) to reduce the risk of myocardial infarction, stroke, and coronary revascularization.
- As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C
- As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C
- As an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C.

APPROVAL CRITERIA[1,2,3]

1. Patient meets FDA labeling age requirement **AND**;
2. Prescribed by or in consultation with a cardiologist **AND**;
3. Patient has the diagnosis of atherosclerotic cardiovascular disease (ASCVD), primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH), or homozygous familial hypercholesterolemia (HoFH) **AND**;
4. Patient has a documented treatment failure to a high-potency statin (atorvastatin or rosuvastatin) at maximum tolerated dose for at least 8 weeks or an intolerance to statin supported by submitted chart notes **AND;**
5. Patient has failed to reach target LDL-C levels (supported by submitted chart notes/labs)
    a. o ASCVD: LDL-C target is < 70 mg/dL
    b. o HeFH or HoFH: LDL-C target is < 100 mg/dL

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. The patient is at or below defined goal LDL-C level prior to initiation of PCSK-9 treatment **OR**;
3. Baseline LDL-C and total cholesterol levels have not been provided

CAUTIONS[1]

- Hypersensitivity reactions, including angioedema, have occurred.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to one year

QUANTITY LIMIT

- Praluent: 150mg every 14 days
- Repatha:
  - ASCVD or HeFH: 140mg every 14 days or 420mg once per 28 days
  - HoFH; 420mg every 14 days

REFERENCES / FOOTNOTES:

1. Praluent (alirocumab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; April 2021
2. Repatha (evolocumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; September 2021
3. Grundy S, Stone N, Bailey A, et.al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2019 Jun, 73 (24) e285–e350