

ALASKA MEDICAID
Prior Authorization Criteria

Praluent® (alirocumab)
Repatha® (evolocumab)

FDA INDICATIONS AND USAGE¹

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

- To reduce the risk of major adverse cardiovascular (CV) events (coronary heart disease death, myocardial infarction, stroke, or unstable angina requiring hospitalization) in adults at increased risk for these events.
- As adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in:
 - adults with hypercholesterolemia
 - adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH)
 - adults with homozygous familial hypercholesterolemia (HoFH)

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

- To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults at increased risk for these events.
- As an adjunct to diet and exercise to reduce low density lipoprotein (LDL-C) in:
 - adults with hypercholesterolemia
 - adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH)
 - adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH)

APPROVAL CRITERIA^{1,2,3}

1. Patient meets FDA labeling age requirement **AND**;
2. Prescribed by or in consultation with a cardiologist **AND**;
3. One or more of the following applies
 - a. Patient has the diagnosis of primary hypercholesterolemia with pre-treatment baseline LDL-C ≥ 190 mg/dl
 - b. Patient has the diagnosis of familial hypercholesterolemia (HeFH or HoFH)
 - c. Is at increased risk for a major adverse cardiovascular event defined as a calculated 10-year ASCVD risk score $\geq 20\%$ **AND**;
4. Patient has a documented treatment failure to a high-potency statin (atorvastatin or rosuvastatin) at maximum tolerated dose for at least 12 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 Non-ASCVD: LDL-C target is < 100 mg/dL

DENIAL CRITERIA¹

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**;

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3. Baseline LDL-C and total cholesterol levels have not been provided **OR**;
4. Product will be used together with another PCSK9 drug.

CAUTIONS¹

- 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.; October 2025
2. Repatha (evolocumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; August 2025
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