AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	PCSK9i Praluent (alirocumab), Repatha (evolocumab)	Page:	1 of 4
Effective Date:	3/6/2026	Last Review Date:	2/2026
Applies to:	☒Illinois ☐New Jersey ☐Pennsylvania Kids	☐Florida Kids ☐Maryland	☐Virginia ☐Michigan

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for PCSK9 inhibitors, Praluent and Repatha, under the patient's prescription drug benefit.

Description:

FDA-approved Indications[1-3]

Praluent

- 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 an 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

- 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 cholesterol (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).

Applicable Drug List:

Praluent
Repatha

Policy/Guideline:

Coverage Criteria

Clinical Atherosclerotic Cardiovascular Disease (ASCVD)[1,2,4,5,9]

Authorization of 12 months may be granted for treatment of ASCVD when all of the following criteria are met:

- Member has a history of ASCVD or has experienced a cardiovascular event.
- Member meets either of the following criteria:
  - Member has a current LDL-C level greater than or equal to 70 milligrams per deciliter.
  - Member has a current LDL-C level greater than or equal to 55 milligrams per deciliter and has multiple ASCVD events or high-risk conditions (e.g., 65 years of age or older, familial hypercholesterolemia, diabetes, chronic kidney disease, history of congestive heart failure).
- Member is receiving maximally tolerated statin therapy or has a contraindication or intolerance to statin therapy.

Hypercholesterolemia[1-5,7]

Authorization of 12 months may be granted for treatment of hypercholesterolemia when all of the following criteria are met:

- Member had an untreated (before any lipid-lowering therapy) LDL-C level greater than or equal to 190 milligrams per deciliter.
- Member has a current LDL-C level greater than or equal to 100 milligrams per deciliter.
- Member is receiving maximally tolerated statin therapy or has a contraindication or intolerance to statin therapy.

Heterozygous Familial Hypercholesterolemia (HeFH)[1-5,7]

Authorization of 12 months may be granted for treatment of heterozygous familial hypercholesterolemia (HeFH) when all of the following criteria are met:

- Member meets either of the following criteria:
  - Member is 18 years of age or older and had an untreated (before any lipid-lowering therapy) LDL-C level greater than or equal to 190 milligrams per deciliter.
  - Member is less than 18 years of age and the request is for Praluent or Repatha, and had an untreated (before any lipid-lowering therapy) LDL-C level greater than or equal to 160 milligrams per deciliter.

- Member has a current LDL-C level greater than or equal to 100 milligrams per deciliter.
- Member is receiving maximally tolerated statin therapy or has a contraindication or intolerance to statin therapy.

Homozygous Familial Hypercholesterolemia (HoFH)[1,2,5,8]

Authorization of 12 months may be granted for treatment of of homozygous familial hypercholesterolemia (HoFH) when all of the following criteria are met:

- Member has a confirmed diagnosis of HoFH.
- Member meets either of the following criteria:
    - Member has a current LDL-C level greater than or equal to 70 milligrams per deciliter.
    - Member has a current LDL-C level greater than or equal to 55 milligrams per deciliter and meets either of the following criteria:
        - Member has a history of a clinical ASCVD event.
        - Member has major ASCVD risk factors (e.g., 65 years of age or older, familial hypercholesterolemia, diabetes, chronic kidney disease, history of congestive heart failure).
- Member is receiving maximally tolerated statin therapy or has a contraindication or intolerance to statin therapy.

Primary Prevention of Atherosclerotic Cardiovascular Disease in Diabetes Mellitus[4,5,9]

Authorization of 12 months may be granted for primary prevention of ASCVD in members with diabetes mellitus when all of the following criteria are met:

- Member is 40 years of age to 75 years of age.
- Member has a current LDL-C level of greater than or equal to 70 milligrams per deciliter.
- Member is receiving maximally tolerated statin therapy or has a contraindication or intolerance to statin therapy.

Continuation of Therapy

Authorization of 12 months may be granted for members who are continuing therapy with a PCSK9i.

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit:

- Praluent 75 mg pen: 2 pens per 28 days
- Repatha 140 mg syringe or Sure Click autoinjector: 3 syringes/ Sure Click per 28 days
- Repatha 420 mg Pushtronex system: 1 injection per 28 days

References:

1. Repatha [package insert]. Thousand Oaks, CA: Amgen, Inc.; August 2025.
2. Praluent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2025.
3. Lerochol [package insert]. Cincinnati, OH: LIB Therapeutics; December 2025.
4. Grundy SM, Stone NJ, Bailey, AL, 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. Circulation. 2019;139(25):e1082–e1143.
5. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2022 ACC Expert consensus decision pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: A report of the American college of cardiologic solution set oversight committee. J Am Coll Cardiol. 2022;80(14):1366–1418.
6. Jacobson TA, Ito MK, Maki KC, et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: part 1 — full report. J Clin Lipidol. 2015;9:(2)129–169.
7. McGowan MP, Hosseini Dehkordi SH, Moriarty PM, et al. Diagnosis and treatment of heterozygous familial hypercholesterolemia. J Am Heart Assoc. 2019; 8(24):e013225.
8. Cuchel M, Raal FJ, Hegele RA, et al. Update on European atherosclerosis society consensus statement on homozygous familial hypercholesterolaemia: new treatments and clinical guidance. Eur Heart J. 2023;44(25):2277-2291.
9. American Diabetes Association Professional Practice Committee. Cardiovascular disease and risk management: standards of care in diabetes – 2024. Diabetes Care. 2024;47(Suppl 1):S179-S218.