



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: PCSK9 Inhibitors

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Effective Date: 10/1/2026

Last Review Date: 9/2026

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 under the patient's prescription drug benefit.

Description:

FDA-Approved Indications¹⁻⁴

Lerochol

As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

Lipfendra

As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

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).



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Applicable Drug List:

Preferred Agent:

Repatha

Non-Preferred Agents:

Lerochol

Lipfendra

Praluent

Policy/Guideline:

Coverage Criteria

Requests for non-preferred agents require that the patient is unable to take Repatha, where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Clinical Atherosclerotic Cardiovascular Disease (ASCVD)^{1,2,5,6,10}

(Praluent and Repatha only)

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 (mg/dL) or a current non-HDL-C greater than or equal to 100 mg/dL.
 - Member has a current LDL-C level greater than or equal to 55 mg/dL or a current non-HDL-C greater than or equal to 85 mg/dL, and has had one of the following:
 - At least two major ASCVD events (e.g., acute coronary syndrome [ACS] within the past 12 months, history of myocardial infarction, history of ischemic stroke, or symptomatic peripheral artery disease).
 - One major ASCVD event and at least two high-risk conditions (e.g., 65 years of age or older, coronary bypass or percutaneous intervention, current smoker, diabetes, history of congestive heart failure, hypertension, or LDL-C of greater than or equal to 100 mg/dL).
 - Chronic kidney disease (CKD) with estimated glomerular filtration rate (eGFR) of 20 milliliters per minute per 1.73 square meters (mL/min/1.73 m²) to 59 mL/min/1.73 m²
- Member is receiving maximally tolerated statin therapy or has a contraindication or intolerance to statin therapy.



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Hypercholesterolemia^{1-6,8}

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 mg/dL in the absence of a secondary cause.
- Member meets either of the following criteria:
 - Member does not have a history of ASCVD and either of the following criteria are met:
 - Member has a current LDL-C level greater than or equal to 70 mg/dL or a current non-HDL-C level greater than or equal to 100 mg/dL in the presence of additional ASCVD risk factors (e.g., 65 years of age or older, coronary bypass or percutaneous intervention, current smoker, diabetes, history of congestive heart failure, hypertension, LDL-C greater than or equal to 100 mg/dL despite maximally tolerated statin and ezetimibe use), heterozygous familial hypercholesterolemia (HeFH), or subclinical atherosclerosis.
 - Member has a current LDL-C level greater than or equal to 100 mg/dL or a current non-HDL-C level greater than or equal to 130 mg/dL in the absence of additional ASCVD risk factors (e.g., 65 years of age or older, coronary bypass or percutaneous intervention, current smoker, diabetes, history of congestive heart failure, hypertension, LDL-C greater than or equal to 100 mg/dL despite maximally tolerated statin and ezetimibe use), HeFH, or subclinical atherosclerosis.
 - Member has a history of clinical ASCVD and a current LDL-C level greater than or equal to 55 mg/dL or a current non-HDL-C level greater than or equal to 85 mg/dL.
- Member is receiving maximally tolerated statin therapy or has a contraindication or intolerance to statin therapy.

Heterozygous Familial Hypercholesterolemia (HeFH)^{1-6,8}

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 mg/dL.
 - 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 mg/dL.



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- Member has a current LDL-C level greater than or equal to 70 mg/dL or a current non-HDL-C level greater than or equal to 100 mg/dL.
- Member is receiving maximally tolerated statin therapy or has a contraindication or intolerance to statin therapy.

Homozygous Familial Hypercholesterolemia (HoFH)^{1,2,6,9}

(Praluent and Repatha only)

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

- Member has a diagnosis of HoFH confirmed by any of the following criteria:
 - Variant in two low-density lipoprotein receptor (LDLR) alleles.
 - Presence of homozygous or compound heterozygous variants in apolipoprotein B (APOB) or proprotein convertase subtilisin-kexin type 9 (PCSK9) gene.
 - Member has compound heterozygosity or homozygosity for variants in the gene encoding low-density lipoprotein receptor adaptor protein 1 (LDLRAP1).
 - Member has an untreated LDL-C of greater than 400 mg/dL and has either of the following:
 - Presence of cutaneous or tendinous xanthomas before the age of 10 years.
 - An untreated LDL-C level of greater than or equal to 190 mg/dL in both parents.
- Member meets either of the following criteria:
 - Member has a current LDL-C level greater than or equal to 100 mg/dL.
 - Member has a current LDL-C level greater than or equal to 55 mg/dL or non-HDL-C level greater than or equal to 85 mg/dL, 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, diabetes, history of congestive heart failure, coronary bypass or percutaneous intervention, current smoker, hypertension, LDL-C greater than or equal to 100 mg/dL despite maximally tolerated statin and ezetimibe use).
- Member is receiving maximally tolerated statin therapy or has a contraindication or intolerance to statin therapy.

Primary Prevention of Atherosclerotic Cardiovascular Disease^{5,6,10,11}

(Praluent and Repatha only)



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Authorization of 12 months may be granted for primary prevention of ASCVD when any of the following criteria is met:

- Member meets all of the following criteria:
 - Member is 40 years of age to 75 years of age.
 - Member has a diagnosis of diabetes mellitus.
 - Member has a current LDL-C level of greater than or equal to 70 mg/dL or a current non-HDL-C level of greater than or equal to 100 mg/dL.
 - Member is receiving maximally tolerated statin therapy or has a contraindication or intolerance to statin therapy.
- Member meets all of the following criteria:
 - Member is 30 years of age to 79 years of age.
 - Member has a 10-year estimated ASCVD risk of greater than or equal to 10% as calculated by the Predicting Risk of Cardiovascular Disease Events – Atherosclerotic Cardiovascular Disease (PREVENT-ASCVD) calculator (see Appendix).
 - Member has a current LDL-C level of greater than or equal to 70 mg/dL or a current non-HDL-C level of greater than or equal to 100 mg/dL.
 - Member is receiving maximally tolerated statin therapy in combination with ezetimibe or has a contraindication or intolerance to statin therapy.
- Member meets all of the following criteria:
 - Member has a coronary artery calcium (CAC) score greater than or equal to 300 Agatston units (AU).
 - Member has a current LDL-C level of greater than or equal to 55 mg/dL or a current non-HDL-C level of greater than or equal to 85 mg/dL.
 - 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:

- Lerochol: 1 syringe per 28 days
- Lipfendra: 30 tablets per 30 days
- Praluent: 2 pens per 28 days



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- Repatha 140 mg syringe or Sure Click autoinjector: 3 syringes/autoinjectors per 28 days
 - Exception limit: 6 syringes/autoinjectors per 28 days
- Repatha 420 mg Pushtronex system: 1 injection per 28 days
 - Exception limit: 2 injections per 28 days

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