

Medical Policy

PCSK9

Last review date: **1/1/2026**

Prior review date: **7/1/2025**

Applicable Products

Leqvio (inclisiran)

Praluent (alirocumab)

Lerochol (lerodalcibep-liga)

Repatha (evolocumab)

Initial Approval Criteria

Coverage may be approved if all of the following are met:

- Disease-specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Leqvio

- Patient has an elevated LDL-C and a diagnosis of:
 - Hypercholesterolemia (must be 18 years of age or older)
 - Heterozygous familial hypercholesterolemia (HeFH) (must be 12 years of age or older)
 - Homozygous familial hypercholesterolemia (HoFH) (must be 12 years of age or older); **AND**
- Prescribed by or in consultation with a cardiologist, endocrinologist, a lipid specialist, etc.; **AND**
- Patient is on high dose statin (atorvastatin 80 mg or rosuvastatin 40 mg) or a maximally tolerated dose with or without ezetimibe for at least 30 days; **AND**
- Patient will not take Leqvio concurrently with other PCSK9 inhibitor(s).

Lerochol

- Patient has an elevated LDL-C and a diagnosis of:
 - Hypercholesterolemia (must be 18 years of age or older)
 - Heterozygous familial hypercholesterolemia (HeFH) (must be 18 years of age or older)
- Prescribed by or in consultation with a cardiologist, endocrinologist, a lipid specialist, etc.; **AND**
- Patient is on high dose statin (atorvastatin 80 mg or rosuvastatin 40 mg) or a maximally tolerated dose with or without ezetimibe for at least 30 days; **AND**
- Patient will not take Lerochol concurrently with other PCSK9 inhibitor(s).

Praluent

- Patient has an elevated LDL-C and a diagnosis of:
 - Hypercholesterolemia (must be 18 years of age or older)
 - Heterozygous familial hypercholesterolemia (HeFH) (must be 8 years of age or older)
 - Homozygous familial hypercholesterolemia (HoFH) (must be 18 years of age or older); **AND**
- Prescribed by or in consultation with a cardiologist, endocrinologist, a lipid specialist, etc.; **AND**
- Patient is on high dose statin (atorvastatin 80 mg or rosuvastatin 40 mg) or a maximally tolerated dose with or without ezetimibe for at least 30 days; **AND**
- Patient will not take Praluent concurrently with other PCSK9 inhibitor(s).

Repatha

- Patient has an elevated LDL-C and a diagnosis of:
 - Hypercholesterolemia (must be 18 years of age or older)
 - Heterozygous familial hypercholesterolemia (HeFH) (must be 10 years of age or older)
 - Homozygous familial hypercholesterolemia (HoFH) (must be 10 years of age or older); **AND**
- Prescribed by or in consultation with a cardiologist, endocrinologist, a lipid specialist, etc.; **AND**
- Patient is on high dose statin (atorvastatin 80 mg or rosuvastatin 40 mg) or a maximally tolerated dose with or without ezetimibe for at least 30 days; **AND**
- Patient will not take Repatha concurrently with other PCSK9 inhibitor(s).

Renewal Criteria

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Absence of unacceptable toxicity

Length of Authorization

1 Year

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.