

# Antihyperlipidemic, Proprotein Convertase Subtilisin Kexin Type 9 (PCSK-9) Inhibitors Criteria

Revised: 04/01/2026

## REPATHA (EVOLOCUMAB) AND PRALUENT (ALIROCUMAB)

**Length of Authorization:** Initial Approvals: 6 months  
Renewals: 1 year

## CHILDREN – CRITERIA TO APPROVE

### Repatha

- **Heterozygous Familial Hypercholesterolemia (HeFH) or Homozygous Familial Hypercholesterolemia (HoFH)**
  - Age 10 to 17 years of age
  - Diagnosis confirmed by mutation in LDL receptor, ApoB, PCSK9, or LDLRAP1 gene locus or ARH adaptor protein gene locus
  - Chart notes documenting **one** of the following:
    - Inadequate response (as confirmed by 12 weeks of paid claims) to both a high intensity statin (e.g., atorvastatin, rosuvastatin) and ezetimibe.
    - Inadequate response (as confirmed by 12 weeks of paid claims) to a statin at the maximally tolerated dose in a member that needs > 25% LDL-C lowering; **OR**
    - Documented contraindication or adverse reaction a high intensity statin (e.g., atorvastatin, rosuvastatin) with or without ezetimibe.
  - Documented lab values of baseline LDL-C within the previous 3 months
  - The medication must be prescribed by or in consultation with a cardiologist or endocrinologist

### Praluent

- **Heterozygous Familial Hypercholesterolemia (HeFH)**
  - **One** of the following:
    - The patient is 8 to 9 years of age; **OR**
    - The patient is 10 to 17 years of age with inadequate response (defined as a paid claim of at least a 30-day supply within the previous 90 days) to Repatha
  - Diagnosis is confirmed by mutation in LDL receptor, ApoB, PCSK9, or LDLRAP1 gene locus or ARH adaptor protein gene locus
  - Chart notes documenting **one** of the following:
    - Inadequate response (as confirmed by 12 weeks of paid claims) to both a high intensity statin (e.g., atorvastatin, rosuvastatin) and ezetimibe.
    - Inadequate response (as confirmed by 12 weeks of paid claims) to a statin at the maximally tolerated dose in a member that needs > 25% LDL-C lowering; **OR**
    - Documented contraindication or adverse reaction a high intensity statin (e.g., atorvastatin, rosuvastatin) with or without ezetimibe.
  - Documented lab values of baseline LDL-C within the previous 3 months

- The medication must be prescribed by or in consultation with a cardiologist or endocrinologist

## ADULTS – CRITERIA TO APPROVE

### Repatha

- **Hypercholesterolemia (including Heterozygous Familial Hypercholesterolemia [HeFH]) and to reduce the risk of major adverse cardiovascular (CV) events.**
  - Age 18 years of age
  - The patient has documented history of **one** of the following:
    - MI, unstable angina, or symptomatic peripheral artery disease
    - Stroke
    - Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH); **OR**
    - A mutation in LDL receptor, ApoB, PCSK9, or LDLRAP1 gene locus or ARH adaptor protein gene locus
  - Chart notes documenting **one** of the following:
    - Inadequate response (as confirmed by 12 weeks of paid claims) to both a high intensity statin (e.g., atorvastatin, rosuvastatin) and ezetimibe.
    - Inadequate response (as confirmed by 12 weeks of paid claims) to a statin at the maximally tolerated dose in a member that needs > 25% LDL-C lowering; **OR**
    - Documented contraindication or adverse reaction a high intensity statin (e.g., atorvastatin, rosuvastatin) with or without ezetimibe.
  - Documented lab values of baseline LDL-C within the previous 3 months
  - The medication must be prescribed by or in consultation with a cardiologist or endocrinologist.
- **Homozygous Familial Hypercholesterolemia (HoFH)**
  - The patient is 18 years of age
  - Diagnosis confirmed by mutation in LDL receptor, ApoB, PCSK9, or LDLRAP1 gene locus or ARH adaptor protein gene locus
  - Chart notes documenting **one** of the following:
    - Inadequate response (as confirmed by 12 weeks of paid claims) to both a high intensity statin (e.g., atorvastatin, rosuvastatin) and ezetimibe.
    - Inadequate response (as confirmed by 12 weeks of paid claims) to a statin at the maximally tolerated dose in a member that needs > 25% LDL-C lowering; **OR**
    - Documented contraindication or adverse reaction a high intensity statin (e.g., atorvastatin, rosuvastatin) with or without ezetimibe.
  - Documented lab values of baseline LDL-C within the previous 3 months
  - The medication must be prescribed by or in consultation with a cardiologist or endocrinologist

### Praluent

- **Homozygous Familial Hypercholesterolemia (HoFH)**
  - The patient is 18 years of age
  - Diagnosis confirmed by mutation in LDL receptor, ApoB, PCSK9, or LDLRAP1 gene locus or ARH adaptor protein gene locus
  - Chart notes documenting **one** of the following:

- Inadequate response (as confirmed by 12 weeks of paid claims) to both a high intensity statin (e.g., atorvastatin, rosuvastatin) and ezetimibe.
- Inadequate response (as confirmed by 12 weeks of paid claims) to a statin at the maximally tolerated dose in a member that needs > 25% LDL-C lowering; **OR**
- Documented contraindication or adverse reaction a high intensity statin (e.g., atorvastatin, rosuvastatin) with or without ezetimibe.
- Documented lab values of baseline LDL-C within the previous 3 months
- Inadequate response (defined as a paid claim of at least a 30-day supply within the previous 90 days) to Repatha.
- The medication must be prescribed by or in consultation with a cardiologist or endocrinologist.
- **Hypercholesterolemia (including Heterozygous Familial Hypercholesterolemia [HeFH]) and to reduce the risk of major adverse cardiovascular (CV) events.**
  - The patient is 18 years of age
  - The patient has documented history of **one** of the following:
    - MI, unstable angina, or symptomatic peripheral artery disease
    - Stroke
    - Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH)); **OR**
    - A mutation in LDL receptor, ApoB, PCSK9, or LDLRAP1 gene locus or ARH adaptor protein gene locus
  - Chart notes documenting **one** of the following:
    - Inadequate response (as confirmed by 12 weeks of paid claims) to both a high intensity statin (e.g., atorvastatin, rosuvastatin) and ezetimibe.
    - Inadequate response (as confirmed by 12 weeks of paid claims) to a statin at the maximally tolerated dose in a member that needs > 25% LDL-C lowering; **OR**
    - Documented contraindication or adverse reaction a high intensity statin (e.g., atorvastatin, rosuvastatin) with or without ezetimibe.
  - Documented lab values of baseline LDL-C within the previous 3 months Inadequate response (defined as a paid claim of at least a 30-day supply within the previous 90 days) to Repatha.
  - The medication must be prescribed by or in consultation with a cardiologist or endocrinologist.

## RENEWAL CRITERIA

**All** the following:

- The patient met initial review requirements
- The patient has an overall clinical improvement in response to therapy including supporting documentation of a decrease in LDL-C levels from baseline (within the previous 3 months); **AND**
- The patient has not experienced any treatment-restricting adverse events.

## REVISION HISTORY

Date	Issues/Updates
04/01/2026	• Initial creation