

## New Hampshire Medicaid Fee-for-Service Program

### Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Criteria

Approval Date: December 3, 2019

#### Indications

Alirocumab is indicated to reduce risk of myocardial infarction (MI), stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease (CVD) as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density-lipoprotein cholesterol (LDL-C).

Evolocumab is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease, as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C) and as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

#### Medications

Brand Name	Generic Name	Dosage Strengths
<b>Praluent®</b>	alirocumab	75 mg and 150 mg single use prefilled pen or syringe
<b>Repatha™</b>	evolocumab	140 mg prefilled autoinjector or syringe -1, 2, and 3 packs

#### Praluent® Criterial for Approval

**ALL** must be met:

1. Prescriber is a cardiologist, lipidologist, or endocrinologist (or one of these specialists has been consulted); **AND**
2. Patient is  $\geq 18$  years of age; **AND**
3. Diagnosis is HeFH as confirmed by genotyping or by clinical criteria (FH using either the Simon Broome, US MedPed Program, or WHO/Dutch Lipid Network criteria); **AND**
4. Maximally tolerated statin will continue to be used in conjunction; **AND**

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5. Prior treatment history with high-intensity statin (atorvastatin or rosuvastatin) **AND** one other cholesterol-lowering agent (such as an alternative high-intensity statin or ezetimibe) for at least 8–12 weeks with failure to reach target LDL-C (70 mg/dL for patients with clinical ASCVD).

## Repatha™ Critical for Approval

**ALL** must be met:

1. Prescriber is a cardiologist, lipidologist, or endocrinologist (or one of these specialists has been consulted); **AND**
2. Patient is  $\geq 18$  years of age; **AND**
3. Diagnosis to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease; **OR**
4. Diagnosis is HeFH as confirmed by genotyping or by clinical criteria (FH using either the Simon Broome, US MedPed Program, or WHO/Dutch Lipid Network criteria); **OR**
5. Patient is  $\geq 13$  years of age; **AND**
6. Diagnosed with HoFH (Repatha™ only) as confirmed by either:
  - a. Documented DNA test for functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality; **OR**
  - b. A history of an untreated LDL-C concentration  $> 500$  mg/dL and triglycerides  $< 300$  mg/dL; **AND**
7. Prior treatment history with high-intensity statin (atorvastatin or rosuvastatin) **AND** one other cholesterol-lowering agent (such as an alternative high-intensity statin or ezetimibe) for at least 8–12 weeks with failure to reach 100 mg/dL for patients with HeFH or HoFH and no history of clinical ASCVD.

## Renewal after initial 6 months for 12 months

1. Lipid panel showing a further reduction in LDL-C compared to the labs prior to initiating therapy; **AND**
2. Continued adherence to maximally tolerated statin dose established prior to the Praluent® approval.

## Criteria for Denial/Renewal

1. Above criteria are not met; **OR**
2. Failure to be compliant with current regimen as documented as no reduction in lipid panel; **OR**
3. No claims history of atorvastatin or rosuvastatin and high-intensity statin or ezetimibe.

## Length of Authorization

Initial six months, extended approval for 12 months if additional criteria are met.

## Quantity Limitation

Praluent® – two pens/syringes per month

Repatha™ – ASCVD or HeFH: two pens or syringes per month

HoFH – three pens or syringes per month

## References

Available upon request.

## Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	05/31/2016
Commissioner	Approval	06/18/2016
DUR Board	Update	09/27/2018
Commissioner Designee	Approval	11/27/2018
DUR Board	Update	10/28/2019
Commissioner Designee	Approval	12/03/2019