New Hampshire Medicaid Fee-for-Service Program

Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Criteria

Approval Date: July 12, 2022

Indications

Alirocumab is indicated to reduce risk of myocardial infarction (MI), stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease (CVD) and as an adjunct to diet and in combination with other low-density-lipoprotein cholesterol (LDL-C) lowering therapy or alone, for the treatment of adults with primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH) who require additional lowering LDL-C. Alirocumab is also indicated as an adjunct to other LDL-C lowering therapies to reduce LDL-C in adult patients with homozygous familial hypercholesterolemia. (HoFH)

Evolocumab is indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease, and as an adjunct to diet, alone, or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe) for the treatment of adults and pediatric patients 10 years of age and older with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C). Evolocumab is also indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in adults and pediatric patients 10 years of age and older with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

Medications

Brand Name	Generic Name	Dosage Strengths
Praluent®	alirocumab	75 mg and 150 mg single use prefilled pen or syringe
Repatha®	evolocumab	140 mg prefilled autoinjector or syringe: 1-, 2-, and 3-packs 420 mg/3.5 mL cartridge

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 ≥ 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. Diagnosed with HoFH 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**

    A history of an untreated LDL-C concentration > 500 mg/dL and triglycerides < 300 mg/dL
6. Maximally tolerated statin will continue to be used in conjunction; **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 target LDL-C 100 mg/dL for patients with HeFH or HoFH and no history of clinical ASCVD.

Repatha™ 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. Diagnosis to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease; **AND**
    a. Patient is ≥ 18 years of age; **OR**
3. Patient is ≥ 10 years of age; **AND**
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. Diagnosed with HoFH 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**
6. 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.

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
DUR Board	Update	12/15/2020
Commissioner Designee	Approval	02/24/2021
DUR Board	Update	06/08/2021
Commissioner Designee	Approval	08/13/2021
DUR Board	Revision	06/02/2022

Reviewed by	Reason for Review	Date Approved
Commissioner Designee	Approval	07/12/2022