New Hampshire Medicaid Fee-for-Service Program Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Criteria

Approval Date: June 5, 2025

Indications

Drug	Indication(s)
Leqvio (inclisiran)	• As an adjunct to diet and statin therapy in adults with HeFH or primary hyperlipidemia who require additional LDL-C reduction
Praluent (alirocumab)	• To reduce the risk of MI, stroke, and unstable angina requiring hospitalization in adults with established atherosclerotic cardiovascular disease (ASCVD) • As adjunct to diet, alone or in combination with other LDL-C-lowering therapies (e.g., statins, ezetimibe), in adults with primary hyperlipidemia, including HeFH, to reduce LDL-C • As an adjunct to other LDL-C-lower therapies in adults with HoFH to reduce LDL-C • As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 8 years and older with HeFH, to reduce LDL-C
Repatha (evolocumab)	• To reduce the risk of major adverse cardiovascular events (MACE) in adults with established CVD • As adjunct to diet, alone or in combination with other LDL-lowering therapies, for treatment of adults with primary hyperlipidemia (including HeFH) to reduce LDL-C • As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C • As an adjunct to other LDL-lowering therapies in adults and pediatric patients aged 10 years and older with HoFH to reduce LDL-C

HeFH – heterozygous familial hypercholesterolemia

HoFH – homozygous familial hypercholesterolemia

Medications

Brand Name	Generic Name	Dosage Strengths
Leqvio	inclisiran	284 mg/1.5 mL single dose prefilled syringe
Praluent	alirocumab	75 mg and 150 mg single use prefilled pen
Repatha	evolocumab	140 mg prefilled autoinjector or syringe: 1-, 2-, and 3-packs 420 mg/3.5 mL cartridge

Criterial for Approval Adults (18 Years of Age and Older)

All must be met:

1. Diagnosis is of primary hyperlipidemia including HeFH; **OR**
2. (Praluent and Repatha): Diagnosed with HoFH; **OR**
3. (Praluent and Repatha): Diagnosis is atherosclerotic cardiovascular disease (ASCVD) to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease; **AND**
4. Maximally tolerated statin will continue to be used in conjunction. Prescriber will provide an attestation if the patient is intolerant to statins; **AND**
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 weeks with failure to reach target LDL-C 100 mg/dL for patients with HeFH or HoFH and no history of clinical ASCVD.

Pediatrics (Under 18 Years of Age)

All must be met:

1. Patients age aligns with FDA indication; **AND**
2. Diagnosis is HeFH; **OR**
3. (Repatha only): Diagnosed with HoFH; **AND**

Prior Treatment

History with at least 1 treatment to lower LDL-C for at least 8–12 weeks with failure to reach 100 mg/dL for patients with HeFH or HoFH. 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

- Leqvio – one syringe per 3 months x 2 doses, then one syringe per 6 months
- 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
Commissioner Designee	Approval	07/12/2022

Reviewed by	Reason for Review	Date Approved
DUR Board	Revision	12/08/2023
Commissioner Designee	Approval	01/22/2024
DUR Board	Revision	04/08/2025
Commissioner Designee	Approval	06/05/2025