New Hampshire Medicaid Fee-for-Service Program

Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) Criteria

Approval Date: January 22, 2024

Indications

Drug	Indication(s)
Leqvio® (inclisiran)	• As an adjunct to diet and maximally tolerated 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
Repatha® (evolocumab)	• To reduce the risk of MI, stroke, and coronary revascularization 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 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. 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 100 mg/dL for patients with HeFH or HoFH and no history of clinical ASCVD.

Leqvio® Criterial for Approval

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 is the following:
    a. 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**
    b. Diagnosis is clinical ASCVD or increased risk of ASCVD requiring additional LDL-C lowering; **AND**
4. Maximally tolerated statin will continue to be used in conjunction; **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 8–12 weeks with failure to reach 100 mg/dL for patients with HeFH or risk of 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

- 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
DUR Board	Revision	12/08/2023
Commissioner Designee	Approval	01/22/2024