



5.40.032

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Cardiovascular Agents	<b>Original Policy Date:</b>	January 21, 2022
<b>Subject:</b>	Leqvio	<b>Page:</b>	1 of 6

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**Last Review Date:** March 6, 2026

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## Leqvio

### Description

#### Leqvio (inclisiran)

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#### Background

Leqvio (inclisiran) is a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin kexin type 9) messenger RNA (mRNA). Leqvio targets the mRNA preventing the synthesis of the PCSK9 protein. PCSK9 binds to the low-density lipoprotein cholesterol (LDL-C) receptors (LDLR) on the surface of hepatocytes to promote LDLR degradation within the liver. By preventing synthesis of PCSK9, more receptors are available to clear LDL cholesterol from the blood, thereby lowering LDL cholesterol levels (1).

#### Regulatory Status

FDA-approved indication: Leqvio is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LCL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH) (1).

Based on the mechanism of action of Leqvio, may cause fetal harm. By reducing the cholesterol levels in circulation, it may also reduce other biologically active substances derived from cholesterol. Leqvio should be discontinued when pregnancy is recognized (1).

The safety and effectiveness of Leqvio in pediatric patients less than 18 years of age have not been established (1).

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#### Related policies

Evkeeza, Juxtapid, Nexletol/Nexlizet, Praluent, Repatha

# 5.40.032

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<b>Subsection:</b>	Cardiovascular Agents	<b>Original Policy Date:</b>	January 21, 2022
<b>Subject:</b>	Leqvio	<b>Page:</b>	2 of 6

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## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Leqvio may be considered **medically necessary** if the conditions indicated below are met.

Leqvio may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age and older

### Diagnoses

Patient must have **ONE** the following:

1. Heterozygous familial hypercholesterolemia (HeFH)
  - a. LDL-C level  $\geq$  100 mg/dL in the past 6 months

**AND ONE** of the following for HeFH:

- a. Confirmed diagnosis by LDL-R DNA Sequencing Test or APOB (hypercholesterolemia) Mutation Analysis
  - b. Dutch Lipid Clinic Network Criteria score  $>$  5
  - c. Simon-Broome Diagnostic Criteria for definite familial hypercholesterolemia
2. Atherosclerotic cardiovascular disease (ASCVD)
    - a. LDL-C level  $\geq$  70 mg/dL in the past 6 months

**AND ONE** of the following for ASCVD:

- a. Patient has had at least **ONE** of the following atherosclerotic cardiovascular disease (ASCVD) or cardiovascular events:
  - i. Acute coronary syndrome (ACS)
  - ii. Myocardial infarction (MI)
  - iii. Stable or unstable angina

# 5.40.032

---

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<b>Subsection:</b>	Cardiovascular Agents	<b>Original Policy Date:</b>	January 21, 2022
<b>Subject:</b>	Leqvio	<b>Page:</b>	3 of 6

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- iv. Coronary or other arterial revascularization procedure (such as PTCA, CABG)
  - v. Transient ischemic attack (TIA)
  - vi. Peripheral arterial disease (PAD) presumed to be of atherosclerotic origin
  - vii. Findings from CT angiogram or catheterization consistent with clinical ASCVD
- b. At high risk for atherosclerotic cardiovascular disease (ASCVD) or cardiovascular event based on 10- year risk score used by **ONE** of the following tools:
- i. ASCVD Pooled Cohort Risk Assessment: score  $\geq 7.5\%$
  - ii. Predicting risk of cardiovascular disease EVENTS (PREVENT): score  $\geq 7.5\%$

**AND ALL** of the following for **ALL** indications:

1. Patient will be assessed for response (i.e., LDL-C reduction) and adherence to the prescribed lipid lowering regimen after 3 months
2. Inadequate treatment response to 3 months of at least **ONE** high intensity statin **OR** patient has an intolerance or contraindication to statin therapy
3. Inadequate treatment response, intolerance, or contraindication to a subtilisin/kexin type 9 (PCSK9) inhibitor
4. **NO** dual therapy with another Prior Authorization (PA) lipid lowering agent (see Appendix 1)

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## Prior-Approval *Renewal* Requirements

**Age** 18 years of age or older

### Diagnoses

Patient must have **ONE** of the following:

1. Heterozygous familial hypercholesterolemia (HeFH)
2. Atherosclerotic cardiovascular disease (ASCVD)

**AND ALL** of the following:

- a. Patient has had **ONE** of the following:

# 5.40.032

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Cardiovascular Agents	<b>Original Policy Date:</b>	January 21, 2022
<b>Subject:</b>	Leqvio	<b>Page:</b>	4 of 6

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- i. Percentage reduction of LDL-C level is  $\geq 40\%$ , compared to the level immediately prior to starting a PCSK9 inhibitor
  - ii. Absolute LDL-C  $< 100\text{mg/dL}$
- b. Patient will be assessed for adherence to the prescribed lipid lowering regimen
- c. **NO** dual therapy with another Prior Authorization (PA) lipid lowering agent (see Appendix 1)

## Policy Guidelines

### Pre-PA Allowance

None

### Prior-Approval Limits

**Quantity** 3 single-dose prefilled syringes

**Duration** 12 months

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### Prior-Approval *Renewal* Limits

**Quantity** 2 single-dose prefilled syringes

**Duration** 12 months

## Rationale

### Summary

Leqvio (inclisiran) is a small interfering RNA (siRNA) therapy targeted to the messenger RNA (mRNA) that codes for proprotein convertase subtilisin kexin type 9 (PCSK9). Leqvio prevents the production of PCSK9 and increases the number of LDL receptors available on the surface of hepatocytes available to bind and degrade LDL-C, thereby reducing LDL cholesterol levels. The safety and effectiveness of Leqvio have not been established in patients younger than 18 years of age (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Leqvio while maintaining optimal therapeutic outcomes.

# 5.40.032

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2026
<b>Subsection:</b>	Cardiovascular Agents	<b>Original Policy Date:</b>	January 21, 2022
<b>Subject:</b>	Leqvio	<b>Page:</b>	5 of 6

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## References

1. Leqvio [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation.; July 2025.

## Policy History

Date	Action
January 2022	Addition to PA
Mach 2022	Annual review
June 2022	Annual review
September 2022	Removed required documentation for HeFH LDL-R DNA sequencing test or APOB mutational analysis. Revised initiation LDL-C levels to drawn level in the past 6 months. Removed required documentation of ASCVD event or high-risk score. Revised requirements for statin inadequate response and intolerances (myalgia, myositis, and hepatotoxicity). Removed required documentation for renewal LDL level.
October 2022	Per FEP, added requirement to try and fail a PCSK9 inhibitor. Changed policy number to 5.40.032
December 2022	Annual review
March 2023	Annual editorial review. Revised wording of no dual therapy requirement for consistency and added Appendix 1
March 2024	Annual review and reference update
March 2025	Annual editorial review and reference update. Per SME, added PREVENT score as an optional ASCVD scoring tool, removed Framingham risk score as an option
June 2025	Annual review
March 2026	Annual editorial review and reference update

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.**

# 5.40.032

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<b>Subsection:</b>	Cardiovascular Agents	<b>Original Policy Date:</b>	January 21, 2022
<b>Subject:</b>	Leqvio	<b>Page:</b>	6 of 6

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## Appendix 1 - List of PA Lipid Lowering Agents

Generic Name	Brand Name
alirocumab	Praluent
bempedoic acid	Nexletol
bempedoic acid/ezetimibe	Nexlizet
evolocumab	Repatha
inclisiran	Leqvio
lomitapide	Juxtapid

\*Dual therapy with Evkeeza (evinacumab-dgnb) is allowed