

<b>Policy Name:</b>	<b>Leqvio (inclisiran)</b>	<b>Policy #:</b>	<b>3133P</b>
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## Purpose of the Policy

The purpose of this policy is to define coverage criteria for Leqvio.

## Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Leqvio under the medical benefit if the following criteria are met.

## Criteria

### 1. Coverage Criteria

- 1.1 Diagnosis of heterozygous familial hypercholesterolemia (HeFH) or high risk of ASCVD (atherosclerotic cardiovascular disease) defined by one of the following:
  - Myocardial infarction (heart attack)
  - Acute coronary syndromes
  - Coronary artery disease
  - Stable or unstable chest pain
  - Coronary or other arterial revascularization
  - Stroke
  - Transient ischemic attack (type of stroke)
  - Peripheral artery disease
- 1.2 Age 18 years or older
- 1.3 Documentation of concurrent statin (such as atorvastatin) use at maximally tolerated dose and ezetimibe (generic for Zetia) for at least 4 months, or contraindication to these medications
- 1.4 Documentation of trial and failure, or contraindication to Praluent or Repatha

### 2. Exclusion Criteria

- 2.1 Leqvio will not be covered if used in combination with PCSK9-inhibitors, Praluent or Repatha

### 3. Approval Period

- 3.1 Initial Period: 12 months
- 3.2 Subsequent Approvals: 12 months with documentation of LDL-C (Low Density Lipoprotein or “bad” cholesterol) reduction and continued use of maximally tolerated statin unless contraindicated

## CPT Codes

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## HCPCS Codes

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## References

1. Leqvio (inclisiran) [prescribing information]. East Hanover, NJ: Novartis Pharmaceutical Corporation; July 2023.
2. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/ AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/ American Heart Association task force on clinical practice guidelines. *Circulation*. 2019;139(25):e1082-e1143..

3. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2022 ACC expert consensus decision pathway on the role of nonstatin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2022;80(14):1366-1418.

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