| Reference number(s) |
| --- |
| 5116-A |

# Medical Prior Authorization
# Leqvio

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Leqvio | inclisiran |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-Approved Indications[1]

Leqvio is indicated as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).

All other indications are considered experimental/investigational and not medically necessary.

## Documentation

Submission of the following information is necessary to initiate the prior authorization review:


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## Initial requests:

- With clinical atherosclerotic cardiovascular disease (ASCVD): Chart notes confirming clinical ASCVD or ASCVD event(s) (if applicable) (see Appendix A).
- Without ASCVD: Untreated (before any lipid lowering therapy) LDL-C level.

## Both initial and continuation requests:

- LDL-C level must be dated within six months preceding the authorization request.
- If member has contraindication or intolerance to statins, chart notes or medical documentation confirming the contraindication or intolerance (see Appendix B).

# Coverage Criteria

## Primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH)[1-6,12]

Authorization of 12 months may be granted for treatment of primary hyperlipidemia when either of the following criteria is met:

- Member meets all of the following criteria:
  - Member has a history of clinical ASCVD (see Appendix A).
  - Member meets either of the following criteria:
    - Member has a current LDL-C level ≥ 70 mg/dL.
    - Member has a current LDL-C level ≥ 55 mg/dL and has multiple ASCVD events (see Appendix A) or high-risk conditions (e.g., 65 years of age or older, familial hypercholesterolemia, diabetes, chronic kidney disease, history of congestive heart failure).
  - Member meets either of the following criteria:
    - Member has received at least three months of treatment with a high-intensity statin. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
    - Member has a contraindication or intolerance to statin therapy (see Appendix B).
  - Member will continue to receive concomitant statin therapy if no contraindication or intolerance (see Appendix B).
- Member meets all of the following criteria:
  - Member had an untreated (before any lipid-lowering therapy) LDL-C level ≥ 190 mg/dL in the absence of a secondary cause.
  - Member has a current LDL-C level ≥ 100 mg/dL.
  - Member meets either of the following criteria:


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    - Member has received at least three months of treatment with a high-intensity statin. If the member is unable to tolerate a high-intensity statin dose, a moderate-intensity statin dose may be used.
    - Member has a contraindication or intolerance to statin therapy (see Appendix B).
- Member will continue to receive concomitant statin therapy if no contraindication or intolerance (see Appendix B).

# Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members (including new members) who meet both of the following criteria:

- Member has achieved or maintained an LDL-C reduction (e.g., LDL-C is now at goal, robust lowering of LDL-C).
- Member will continue to receive concomitant statin therapy if no contraindication or intolerance (see Appendix B).

# Appendix

## Appendix A. Clinical ASCVD[5-7,10,11]

- Acute coronary syndromes
- Myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization procedure (e.g., percutaneous coronary intervention [PCI], coronary artery bypass graft [CABG] surgery)
- Stroke of presumed atherosclerotic origin
- Transient ischemic attack (TIA)
- Non-cardiac peripheral arterial disease (PAD) of presumed atherosclerotic origin (e.g., carotid artery stenosis, lower extremity PAD)
- Obstructive coronary artery disease (defined as ≥ 50% stenosis on cardiac computed tomography angiogram or catheterization)
- Coronary artery calcium (CAC) Score ≥ 300

## Appendix B. Contraindications to statin therapy [6,8,9]

- Score of 7 or higher on the Statin-Associated Muscle Symptom Clinical Index (SAMS-CI) and failed statin rechallenge
- Presence of statin-associated muscle symptoms with elevation in creatine kinase (CK) level > 3 times upper limit of normal (ULN)


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- Statin-associated elevation in creatine kinase (CK) level ≥ 10 ULN
- Active liver disease, including unexplained persistent elevations in hepatic transaminase levels (e.g., alanine transaminase [ALT] level ≥ 3 times ULN)
- Pregnancy or planned pregnancy
- Breastfeeding

# References

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7. Min JK, Labounty TM, Gomez MJ, et al. Incremental prognostic value of coronary computed tomographic angiography over coronary artery calcium score for risk prediction of major adverse cardiac events in asymptomatic diabetic individuals. Atherosclerosis. 2014;232(2):298-304.
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12. American Diabetes Association Professional Practice Committee. Cardiovascular disease and risk management: standards of care in diabetes – 2024. Diabetes Care. 2024;47(Suppl 1):S179-S218.


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