Leqvio (inclisiran)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Leqvio (inclisiran) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. 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

Leqvio is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in:

- Adults with hypercholesterolemia
- Adults and pediatric patients aged 12 years and older with heterozygous familial hypercholesterolemia (HeFH)
- Pediatric patients aged 12 years and older with homozygous familial hypercholesterolemia (HoFH)

POLICY

Prescriber Requirement

The medication must be prescribed by or in consultation with a cardiologist, endocrinologist, lipid specialist, or cardiometabolic specialist.

Required Documentation

The following information is necessary to initiate the prior authorization review:

- Untreated baseline LDL level, LDL levels while receiving statin therapy (prior to starting Leqvio), and current LDL levels on Leqvio (if applicable)
- Untreated baseline apolipoprotein B (apoB), apoB level while receiving statin therapy (prior to starting Leqvio)
- Chart notes demonstrating the member is engaging in healthy lifestyle changes (e.g., heart-healthy diet and exercise regimen)
- Chart notes demonstrating statin intolerance or contraindication to statin therapy (if applicable)
- For clinical atherosclerotic cardiovascular disease (ASCVD), chart notes confirming clinical ASCVD (Appendix A).
- For prevention of ASCVD: documentation of ASCVD risk score using PREVENT-ASCVD equations, risk enhancers or another clinically appropriate risk score and/or calculator
- For heterozygous familial hypercholesterolemia: genetic testing or medical records (Appendix E or F) confirming the diagnosis of HeFH including untreated (before any lipid lowering therapy) LDL-C level.
- For homozygous familial hypercholesterolemia: genetic testing (i.e., LDL-receptor [LDLR], apolipoprotein B [ABOB], proprotein convertase substilisin/Kexin type 9 [PCSK9], or LDL-receptor adaptor protein 1 [LDLRAP1]), or medical records demonstrating HoFH diagnosis

Criteria for Initial Approval

A. **Leqvio** (inclisiran) may be considered **medically necessary** for the treatment of **clinical atherosclerotic cardiovascular disease (ASCVD)** or for the **prevention of ASCVD** for members at high risk when **ALL** of the following criteria are met:

1. Member is 18 years of age or older
2. Member has a history of one of the following:
    a. Clinical ASCVD (Appendix A)
    b. High-risk for ASCVD with one of the following:
        i. PREVENT-ASVCD equations calculate a 10-year ASCVD risk score ≥ 10%
        ii. PREVENT-ASCVD equations calculate an intermediate 10-year ASCVD risk score of 5% to <10% and the presence of one or more ASCVD risk enhancers (Appendix B)
        iii. PREVENT-ASCVD 10-year ASCVD risk score is expected to underestimate the member's risk for ASCVD and an alternative risk score (i.e., MESA, Qrisk3) calculates a 10-year risk score ≥ 10%
        iv. Member has diabetes and is at higher cardiovascular risk
3. Member is engaging in healthy lifestyle changes
4. Member has one of the following laboratory values despite adherence to the combination of lifestyle changes and at least three months of maximally tolerated high-intensity statin therapy:
    a. A current low-density lipoprotein cholesterol (LDL-C) ≥ 70 mg/dL
    b. A current LDL-C level ≥ 55 mg/dL with history of multiple clinical atherosclerotic cardiovascular disease (ASCVD) events or one major ASCVD event and multiple high-risk conditions (See Appendix C)
    c. An apolipoprotein B ≥ 80 mg/dL
5. Leqvio will not be combined with other PCSK9-targeted therapy (e.g., Lerochol, Repatha, Praluent)
6. Dose does not exceed 284 mg initially and at 3 months, then every 6 months thereafter

OR

1. Member is 18 years of age or older
2. Member has a history of one of the following:

a. Clinical ASCVD (Appendix A)
b. High-risk for ASCVD with one of the following:
    i. PREVENT-ASVCD equations calculate a 10-year ASCVD risk score ≥ 10%
    ii. PREVENT-ASCVD equations calculate an intermediate 10-year ASCVD risk score of 5% to <10% and the presence of one or more ASCVD risk enhancers (Appendix B)
    iii. PREVENT-ASCVD 10-year ASCVD risk score is expected to underestimate the member's risk for ASCVD and an alternative risk score (i.e., MESA, Qrisk3) calculates a 10-year risk score ≥ 10%
    iv. Member has diabetes and is at higher cardiovascular risk

3. Member is engaging in healthy lifestyle changes
4. Member has one of the following laboratory values:
    a. A current LDL-C level ≥ 70 mg/dL
    b. A current LDL-C level ≥ 55 mg/dL with history of multiple clinical atherosclerotic cardiovascular disease (ASCVD) events or one major ASCVD event and multiple high-risk conditions (See Appendix C)
    c. An apolipoprotein B ≥ 80 mg/dL
5. Member has a documented contraindication (e.g., active liver disease, pregnancy, breastfeeding), or medically justifiable reason that precludes statin use (e.g., member has experienced rhabdomyolysis, CK elevations ≥ 10x ULN, or statin intolerance defined in accordance with the National Lipid Association [Appendix D])
6. Leqvio will not be combined with other PCSK9-targeted therapy (e.g., Lerochol, Repatha, Praluent)
7. Dose does not exceed 284 mg initially and at 3 months, then every 6 months thereafter

B. Leqvio (inclisiran) may be considered **medically necessary** for the treatment of **heterozygous familial hypercholesterolemia (HeFH)** when ALL the following criteria are met:

1. Member is 12 years of age or older
2. Member has a diagnosis of HeFH, which is documented and confirmed by ONE of the following:
    a. A pathogenic variant in the LDL-receptor (LDLR), apolipoprotein B (ABOB), proprotein convertase substilisin/Kexin type 9 (PCSK9), or LDL-receptor adaptor protein 1 (LDLRAP1); or
    b. Definite FH per Simon-Broome Diagnostic Criteria (Appendix E)
    c. Dutch Lipid Network Criteria score greater than 8 points (Appendix F)
    d. Definite FH per US Make Early Diagnosis to Prevent Early Death (MEDPED) Diagnostic Criteria
3. Member is engaging in healthy lifestyle changes
4. Member has been unable to achieve an LDL-C < 70 mg/dL (or < 55 mg/dL with history of multiple clinical atherosclerotic cardiovascular disease [ASCVD] events or one major ASCVD event and multiple high-risk conditions [See Appendix C]) despite adherence to the combination of lifestyle changes and at least three months of maximally tolerated high-intensity statin therapy
5. Leqvio will not be combined with other PCSK9-targeted therapy (e.g., Lerochol, Repatha, Praluent)
6. Dose does not exceed 284 mg initially and at 3 months, then every 6 months thereafter

OR

1. Member is 12 years of age or older
2. Member has a diagnosis of HeFH, which is documented and confirmed by ONE of the following:

a. A pathogenic variant in the LDL-receptor (LDLR), apolipoprotein B (ABOB), proprotein convertase substilisin/Kexin type 9 (PCSK9), or LDL-receptor adaptor protein 1 (LDLRAP1); or
b. Definite FH per Simon-Broome Diagnostic Criteria (Appendix E)
c. Dutch Lipid Network Criteria score greater than 8 points (Appendix F)
d. Definite FH per US Make Early Diagnosis to Prevent Early Death (MEDPED) Diagnostic Criteria

3. Member is engaging in healthy lifestyle changes
4. Member has a current LDL-C level ≥ 70 mg/dL (or current LDL-C level ≥ 55 mg/dL with history of multiple clinical atherosclerotic cardiovascular disease [ASCVD] events or one major ASCVD event and multiple high-risk conditions [See Appendix C])
5. Member has a documented contraindication (e.g., active liver disease, pregnancy, breastfeeding), or medically justifiable reason that precludes statin use (e.g., patients has experienced rhabdomyolysis, CK elevations ≥ 10x ULN, or statin intolerance defined in accordance with the National Lipid Association [Appendix D]).
6. Leqvio will not be combined with other PCSK9-targeted therapy (e.g., Lerochol, Repatha, Praluent)
7. Dose does not exceed 284 mg initially and at 3 months, then every 6 months thereafter

C. Leqvio (inclisiran) may be considered **medically necessary** for the treatment of **homozygous familial hypercholesterolemia (HoFH)** when the following criteria are met:

1. Member is between 12 and <18 years of age
2. Member has a definite diagnosis of HoFH, which is documented and confirmed by ONE of the following:
   a). Mutation in both alleles at LDL receptor (LDLR), ApoB, PCSK9 or LDL receptor adaptor protein 1 (LDLRAP1) gene locus or ≥2 such mutations at different loci (Appendix G); **OR**
   b). Untreated low-density lipoprotein-cholesterol (LDL-C) >400 mg/dL plus one of the following:
      i. Tendon or cutaneous xanthomas before age 10
      ii. Definite familial hypercholesterolemia (FH) by Simon-Broome Diagnostic Criteria, Dutch Lipid Clinic Network Criteria, or US Make Early Diagnosis to Prevent Early Death (MEDPED) Diagnostic Criteria in both parents (Appendix E and F)
3. Member has been unable to achieve an LDL-C reduction of ≥ 50% despite adherence to at least three months of maximally tolerated high-intensity statin therapy
4. The requested medication will not be combined with other PCSK9-targeted therapy (e.g., Lerochol, Praluent, Repatha) or Juxtapid
5. Dose does not exceed 284 mg initially and at 3 months, then every 6 months thereafter

OR

1. Member is between 12 and <18 years of age
2. Member has a definite diagnosis of HoFH, which is documented and confirmed by ONE of the following:
   a). Mutation in both alleles at LDL receptor (LDLR), ApoB, PCSK9 or LDL receptor adaptor protein 1 (LDLRAP1) gene locus or ≥2 such mutations at different loci (Appendix G); **OR**
   b). Untreated LDL-C > 400 mg/dL plus one of the following:
      i. Tendon or cutaneous xanthomas at age 10 or younger
      ii. Definite FH by Simon-Broome Diagnostic Criteria, Dutch Lipid Clinic Network Criteria, or US Make Early Diagnosis to Prevent Early Death (MEDPED) Diagnostic Criteria in both parents (Appendix E and F)

3. Member has a documented contraindication (e.g., active liver disease, pregnancy, breastfeeding), or a medically justifiable reason that precludes statin use (e.g., member has experienced rhabdomyolysis, creatine kinase [CK] elevations ≥ 10x ULN, or statin intolerance as defined in accordance with the National Lipid Association definition [Appendix D])
4. The requested medication will not be combined with other PCSK9-targeted therapy (e.g., Lerochol, Praluent, Repatha) or Juxtapid
5. Dose does not exceed 284 mg initially and at 3 months, then every 6 months thereafter

D. **Leqvio** (inclisiran) may be considered **medically necessary** for the treatment of **primary hyperlipidemia** when ALL the following criteria are met:

1. Member is 18 years of age or older
2. Member has a diagnosis of primary hyperlipidemia in which both of the following criteria are met:
   a. Member had an untreated LDL-C level ≥ 160 mg/dL
   b. Member does not have a secondary cause of hyperlipidemia
3. Member is engaging in healthy lifestyle changes
4. Member has been unable to achieve an LDL-C < 70 mg/dL despite adherence to the combination of lifestyle changes and at least three months of maximally tolerated high-intensity statin therapy
5. Leqvio will not be combined with other PCSK9-targeted therapy (e.g., Lerochol, Repatha, Praluent)
6. Dose does not exceed 284 mg initially and at 3 months, then every 6 months thereafter

OR

1. Member is 18 years of age or older
2. Member has a diagnosis of primary hyperlipidemia and meets both of the following:
   a. Member had an untreated LDL-C level ≥ 160 mg/dL
   b. Member does not have a secondary cause of hyperlipidemia
3. Member is engaging in healthy lifestyle changes
4. Member has a current LDL-C level ≥ 70 mg/dL
5. Member has a documented contraindication (e.g., active liver disease, pregnancy, breastfeeding), or medically justifiable reason that precludes statin use (e.g., member has experienced rhabdomyolysis, CK elevations ≥ 10x ULN, or statin intolerance defined in accordance with the National Lipid Association [Appendix D]).
6. Leqvio will not be combined with other PCSK9-targeted therapy (e.g., Lerochol, Repatha, Praluent)
7. Dose does not exceed 284 mg initially and at 3 months, then every 6 months thereafter

Initial approval will be for **9 months**

Continuation of Therapy

The continuation of therapy for Leqvio may be considered **medically necessary** for any member who meets the following criteria:

- Must have a documented positive clinical response to therapy as defined by achieving or maintaining an LDL-C reduction (i.e., LDL-C is now at goal or 50% reduction of LDL-C from baseline); **AND**
- Member continues to engage in healthy lifestyle changes
- Leqvio will not be combined with other PCSK9-targeted therapy (e.g., Lerochol, Repatha, Praluent) or Juxtapid (if applicable)

- Dose does not exceed 284 mg every 6 months

Renewals will be approved for **12 months**

†Please note: Documentation of LDL-C levels are required (untreated baseline and current [within 90 days of prior authorization request])

Leqvio is considered **not medically necessary** for members who do not meet the criteria set forth above.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

APPENDIX

APPENDIX A: Clinical Atherosclerotic Cardiovascular Disease (ASCVD)

- 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)
- Lower-extremity peripheral arterial disease (PAD) or other atherosclerotic forms of PAD including aortic aneurysm
- Obstructive coronary artery disease (defined as fifty percent or greater stenosis on cardiac computed tomography angiogram or catheterization)
- Coronary Artery Calcium (CAC) Score ≥ 300

APPENDIX B: ASCVD Risk Enhancers

- Family history of premature ASCVD in a parent or sibling (males, age <55 years; females, age <65 years)

- Higher risk ancestry (e.g., South Asian, Filipino)
- High polygenic risk (if measured)
- Chronic inflammatory diseases (e.g., systemic lupus, RA, advanced psoriasis, inflammatory arthritis)
- Lp(a) ≥125 nmol/L or ≥50 mg/dL
- hs-CRP ≥2.0 mg/L on > 1 occasion (if measured)
- TG persistently ≥175 mg/dL (2 mmol/L) (if nonfasting) and ≥150 mg/dL (1.7 mmol/L) (if fasting)
- CKM syndrome
- LDL-C persistently ≥160-189 mg/dL (4.1-4.9 mmol/L), non-HDL-C ≥190-219 mg/dL or apoB ≥120 mg/dL
- Reproductive risk markers (premature menopause, preeclampsia, gestational diabetes, gestational hypertension, preterm delivery)

APPENDIX C: Criteria for Identifying Patients at Very High Risk* of ASCVD Events

Major ASCVD Events	Acute coronary syndrome within the past 12 months
	History of myocardial infarction
	History of ischemic stroke
	Symptomatic PAD (claudication with ABI <0.85 or previous revascularization of amputation)
High-Risk Conditions	Age ≥ 65 years
	History of prior coronary artery bypass surgery or PCI outside of the major ASCVD event(s)
	Diabetes
	Hypertension
	Current smoker
	Persistently elevated LDL-C (≥100 mg/dL [≥2.6 mmol/L]) despite maximally tolerated statin therapy and ezetimibe
	History of congestive HF

*Very high risk includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions.

APPENDIX D: Statin intolerance in accordance with the National Lipid Association definition

Inability to tolerate at least two statins (one at any dose, one at lowest daily dose) due to objectionable symptoms or abnormal biomarkers temporally related to statin use, reversible upon statin discontinuation and reproducible by re-challenge while excluding other known determinants. Other known determinants include low body mass index (BMI), acute infection, untreated or undertreated hypothyroidism, severe renal or hepatic dysfunction, organ transplant, recent severe trauma, HIV infection, Vitamin D deficiency, history of CK elevation, preexisting or unexplained muscle or joint pain, high level of physical activity, illicit drug abuse, excess alcohol use. Each statin trial, both initial and re-challenge shall be at least two weeks duration.

- A trial of one statin at lowest starting daily dose
  - Rosuvastatin 5mg
  - Atorvastatin 10mg
  - Simvastatin 10mg
  - Lovastatin 20mg
  - Pravastatin 40mg
  - Fluvastatin 40mg
  - Pitavastatin 2mg
- One statin at any daily dose

APPENDIX E: Simon Broome Register diagnostic criteria for Familial Hypercholesterolemia

Definite familial hypercholesterolemia:

- Total cholesterol > 290 mg/dL or LDL-C > 190 mg/dL in patients over 16 years of age or total cholesterol > 260 mg/dL or LDL-C > 155 mg/dL in patients less than 16 years of age

AND

- Tendon xanthomas in the patient, first (parent, sibling or child) or second degree relative (grandparent, uncle or aunt); OR presence LDL-receptor mutation, familial defective apo B-100, or a PCSK9 mutation.

Possible familial hypercholesterolemia:

- Total cholesterol > 290 mg/dL or LDL-C > 190 mg/dL in patients over 16 years of age or total cholesterol > 260 mg/dL or LDL-C > 155 mg/dL in patients less than 16 years of age

AND

- Family history of at least one of the following:
  - Family history of myocardial infarction at age 60 years or younger in first degree relative or age 50 years or younger in second-degree relative

  OR

  - Family history of elevated total cholesterol of greater than 290 mg/dL in adult first- or second-degree relative or total cholesterol greater than 260 mg/dL in child, brother or sister aged younger than 16 years

APPENDIX F: Dutch Lipid Clinic Network diagnostic criteria for Familial Hypercholesterolemia

Diagnostic Scoring for Familial Hypercholesterolemia			
Family History			
First degree relative with known premature (men < 55 yrs, women < 60 yrs) coronary vascular disease			1
First degree relative with known LDL-cholesterol >95th percentile for age and sex			
and/or			
First degree relative with tendon xanthomata and/or arcus cornealis			2
Children below 18 yrs with LDL-cholesterol >95th percentile for age and sex			
Clinical History			
Patient has premature (men < 55 yrs, women < 60 yrs) coronary artery disease			2
Patient has premature (men < 55 yrs, women < 60 yrs) cerebral or peripheral vascular disease			1
Physical Examination			
Tendon xanthomata			6
Arcus cornealis below the age of 45 yrs			4
Laboratory Analysis			
	mmol/L	mg/dL	
LDL-cholesterol	> 8.5	> 330	8
LDL-cholesterol	6.5 – 8.4	250 – 329	5
LDL-cholesterol	5.0 – 6.4	190 – 249	3
LDL-cholesterol	4.0 – 4.9	155 – 189	1
(HDL-cholesterol and triglycerides are normal)			
DNA Analysis			
Functional mutation in the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B) or proprotein convertase subtilisin/kexin type 9 (PCSK9) gene			8
Diagnosis of FH is:			
Certain When		> 8 points	
Probable When		6-8 points	
Possible When		3-5 points	
Unlikely When		<3 points	

APPENDIX G: Sources of genetic complexity of phenotypic homozygous familial hypercholesterolemia (FH)

Genetic heterogeneity:

LDLR gene loss-of-function variants
ApoB gene-receptor-binding-impaired variants
PCSK9 gene gain-of-function variants
LDLRAP1 gene loss-of-function variants

Variable inheritance patterns:

Semi-dominant (i.e., LDLR, ApoB, PCSK9 genes)
True autosomal recessive (i.e., LDLRAP1 gene)

Variant types:

'Null' variant of LDLR (i.e., copy number variants, nonsense variant resulting in premature termination, splicing variant)
'Defective' variant of LDLR (i.e., missense variant altering a single amino acid residue)

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD-CM diagnostic codes.

- J1306 - Injection, inclisiran, 1 mg

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*Some content reprinted from CVSHealth

POLICY HISTORY

Policy #: 05.04.60
Policy Creation: April 2022
Reviewed: April 2026
Revised: April 2026
Current Effective Date: June 6, 2026