

inclisiran (Leqvio)

HCPs: J1306 - Injection, inclisiran, 1mg (Leqvio)

LOB:	MCAL
Duration of Approval:	One year
Quantity Limit:	Per FDA Approved/Compendia Supported Dosing
MCG Available:	No
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

Leqvio (inclisiran) injection

PA CRITERIA FOR APPROVAL:**New Therapy**

1. The member has a diagnosis for an FDA-approved indication (*refer to package insert under References*) OR a compendia-supported (Drugdex or AHFS) indication
AND
2. The medication is prescribed or recommended by a cardiologist, endocrinologist or lipid specialist
AND
3. The member has a history of failure, contraindications or reasons for intolerance to a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Repatha [evolocumab] or Praluent [alirocumab])
AND
4. The member meets **ONE** of the following (**a or b**):
 - a. History of failure (at least eight weeks of adherent therapy) to at least **TWO** maximally tolerated dose of high intensity statin therapy (e.g., atorvastatin $\geq$ 40 mg, rosuvastatin $\geq$ 20 mg or simvastatin $\geq$ 40 mg) with or without ezetimibe
 - b. Statin intolerance documented by:
 - 1) Adverse effects to any TWO statins (at least ONE at the lowest dose) such as myositis/myopathy (with creatine kinase above 10x upper limit of normal [ULN]) or persistent elevation of hepatic transaminase (alanine aminotransferase [ALT] or aspartate aminotransferase [AST] 3x above the ULN) **OR**
 - 2) History of statin-associated rhabdomyolysis **OR** immune-mediated necrotizing myopathy (presence of 3-hydroxy-3-methylglutaryl- coenzyme [HMG-CoA] reductase antibodies) to any one statin**NOTE:** Rhabdomyolysis is statin-induced muscle breakdown that is associated with markedly elevated creatine kinase levels (at least 10 times the ULN), along with evidence of end organ damage which can include signs of acute renal injury (noted by substantial increases in serum creatinine [Scr] levels [a 0.5 mg/dL or more increase in Scr or doubling of the Scr] and/or myoglobinuria [myoglobin present in urine]).**AND**
5. For hypercholesterolemia: ALL of the following are met (**a and b**):
 - a. The member meets ONE of the following (**1 or 2**):
 - 1) The member has a diagnosis of atherosclerotic cardiovascular disease (ASCVD) (i.e., coronary heart disease [myocardial infarction, angina pectoris], cerebrovascular disease [nonhemorrhagic stroke, transient ischemic attack], peripheral arterial disease, aortic atherosclerosis)
 - 2) The member has ASCVD-risk equivalents (i.e., type 2 diabetes, familial hypercholesterolemia, or > 20% for 10-year risk of a CV event assessed) by Framingham Risk Score [[calculator](#)]
 - b. The member has baseline LDL $\geq$ 70 mg/dL (for those with ASCVD) or LDL $\geq$ 100 mg/dL (for those with ASCVD-risk equivalent)**OR**
6. For heterozygous familial hypercholesterolemia (HeFH): ALL of the following are met (**a and b**):
 - a. Diagnosis has been confirmed by ONE of the following:

inclisiran (Leqvio)

HCPCS: J1306 - Injection, inclisiran, 1mg (Leqvio)

- 1) Positive genetic testing to confirm mutation in the low-density lipoprotein receptor (LDL-R) gene, pathogenic variants of the apolipoprotein (ApoB) gene, mutations in (PCSK9) or homozygous mutations in the LDL-R adaptor protein-1
 - 2) History of LDL-C > 190 mg/dL **AND** a first-degree relative with familial hypercholesterolemia, elevated cholesterol or early heart disease that may indicate familial hypercholesterolemia
 - 3) A [Dutch Lipid Clinic Network Criteria](#) score of ≥ six
 - 4) A diagnosis of a “definite” or “probable” FH per the [Simon Broome FH diagnostic criteria](#)
 - b. Current fasting LDL ≥ 100 mg/dL
- OR**
7. For homozygous familial hypercholesterolemia (HoFH): ALL of the following are met (**a-c**):
 - a. The member is 12 to 17 years old
 - b. Diagnosis has been confirmed by ONE of the following (**1 or 2**):
 - 1) Genetic test showing mutation(s) in low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality (i.e. LDLR, LDLRAP1, PCSK9, or apoB gene
 - 2) The member has untreated LDL level > 400 mg/dL or treated LDL level ≥ 300 mg/dL AND meets ONE of the following:
 - a) Cutaneous or tendon xanthomas before age of 10 years
 - b) Untreated elevated LDL-C levels consistent with heterozygous FH in both parents
 - c. Current fasting LDL > 130mg/dL

Continuation of Therapy

1. The member has a diagnosis for an FDA-approved indication (*refer to package insert under References*) OR a compendia-supported (Drugdex or AHFS) indication
- AND**
2. Documentation is provided showing positive response to therapy such as reduction of LDL from baseline

OTHER INFORMATION:

HCPCS	Description	Brand name
J1306	Injection, inclisiran, 1mg	Leqvio

REFERENCES:

1. Leqvio Prescribing Information: www.novartis.com/us-en/sites/novartis_us/files/leqvio.pdf. 02/2026.
2. The Medicines Company. Inclisiran for Participants with Atherosclerotic Cardiovascular Disease and Elevated Low-Density Lipoprotein Cholesterol (ORION-10). NLM Identifier: NCT03399370. Study Protocol. cdn.clinicaltrials.gov/large-docs/70/NCT03399370/Prot_000.pdf.
3. The Medicines Company. Inclisiran for Subjects with ASCVD or ASCVD-Risk Equivalents and Elevated Low-density Lipoprotein Cholesterol (ORION-11). NLM Identifier: NCT03400800. Study Protocol. cdn.clinicaltrials.gov/large-docs/00/NCT03400800/Prot_000.pdf.
4. Trial to Evaluate the Effect of Inclisiran Treatment on Low Density Lipoprotein Cholesterol (LDL-C) in Subjects with Heterozygous Familial Hypercholesterolemia (HeFH) (ORION-9). NLM Identifier: NCT03397121. Study Protocol. cdn.clinicaltrials.gov/large-docs/21/NCT03397121/Prot_000.pdf.
5. Novartis Pharmaceuticals. Study to Evaluate Efficacy and Safety of Inclisiran in Adolescents with Heterozygous Familial Hypercholesterolemia (ORION-16). NLM Identifier: NCT04652726. Study Protocol. cdn.clinicaltrials.gov/large-docs/26/NCT04652726/Prot_000.pdf.
6. Cuchel M, Raal FJ, Hegele RA, et al. 2023 Update on European Atherosclerosis Society Consensus Statement on Homozygous Familial Hypercholesterolaemia: new treatments and clinical guidance. Eur Heart J. 2023;44(25):2277-2291. www.ncbi.nlm.nih.gov/pmc/articles/PMC10314327/pdf/ehad197.pdf.

inclisiran (Leqvio)

HCPs: J1306 - Injection, inclisiran, 1mg (Leqvio)

7. McGowan MP, Dehkordi SHH, Moriarty PM, et al. Diagnosis and Treatment of Heterozygous Familial Hypercholesterolemia. Journal of the American Heart Association. Dec. 2019; 8(24): e013225.
www.ahajournals.org/doi/epub/10.1161/JAHA.119.013225.
8. IV. General Approach to Treatment-Goals and Thresholds. Circulation Dec. 2002 106(25): 3243-3250.
www.ahajournals.org/doi/epub/10.1161/circ.106.25.3243.

UMC REVIEW:

6/2026