

Leqvio® (inclisiran subcutaneous injection)

When requesting Leqvio® (inclisiran), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indications

Leqvio is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with the following:

- Clinical atherosclerotic cardiovascular disease (ASCVD) for those who require additional lowering of low-density lipoprotein cholesterol (LDL-C)
- Heterozygous familial hypercholesterolemia (HeFH) for those who require additional lowering of LDL-C.

Coverage Guidelines

Atherosclerotic Cardiovascular Disease

The individual must meet **all** of the following criteria for approval:

- Patient is at least 18 years of age; AND
- Patient has had one of the following conditions or diagnoses:
 - A previous myocardial infarction or a history of an acute coronary syndrome; OR
 - Angina (stable or unstable); OR
 - A past history of stroke or transient ischemic attack; OR
 - Peripheral arterial disease; OR
 - Patient has undergone a coronary or other arterial revascularization procedure in the past (e.g., coronary artery bypass graft surgery, percutaneous coronary intervention, angioplasty, and coronary stent procedure); AND
- Patient meets one of the following criteria:
 - Patient has tried one high-intensity statin therapy (i.e., atorvastatin $\geq$ 40 mg daily; rosuvastatin $\geq$ 20 mg daily [as a single entity or as a combination product]); AND
 - Patient has tried one high-intensity statin along with ezetimibe (as a single-entity or as a combination product) for $\geq$ 8 continuous weeks; AND
 - LDL-C level after this treatment regimen remains $\geq$ 70mg/dL; OR
 - Patient has been determined to be statin intolerant by meeting one of the following criteria:
 - Patient experienced statin-related rhabdomyolysis (*note: rhabdomyolysis is associated with elevated creatine kinase levels at least 10 times the upper limit of normal, along with evidence of end organ damage which can include signs of acute renal injury [a $\geq$ 0.5 mg/dL increase in serum creatinine {Scr} levels or doubling of the Scr] and/or myoglobinuria [myoglobin present in urine]; OR*
 - Patient experienced skeletal-related muscle symptoms (*Note: Skeletal-related muscle symptoms include myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]; AND*

- The skeletal-related muscle symptoms occurred while receiving separate trials of both atorvastatin and rosuvastatin (as a single-entity or as combination products); AND
- When receiving separate trials of both atorvastatin and rosuvastatin (as a single-entity or as combination products) the skeletal-related muscle symptoms resolved upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin) (*Note: skeletal muscle symptoms include myopathy and myalgia*); AND
- This medication is prescribed by, or in consultation with, a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular risk management and/or lipid disorders.

Heterozygous Familial Hypercholesterolemia

The individual must meet **all** of the following criteria for approval:

- Patient is at least 18 years of age; AND
- Patient meets one of the following criteria:
 - Patient has an untreated LDL-C level ≥ 190 mg/dL (prior to treatment with antihyperlipidemic agents); OR
 - Patient has genetic confirmation of heterozygous familial hypercholesterolemia by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene; OR
 - Patient has been diagnosed with HeFH meeting one of the following diagnostic criteria thresholds:
 - Prescriber used the Dutch Lipid Network criteria to diagnose HeFH; AND
 - Patient had a score > 5 ; OR
 - Prescriber used the Simon Broome criteria to diagnose HeFH; AND
 - Patient met the threshold for “definite” or “possible (or probable)” familial hypercholesterolemia; AND
- Patient meets one of the following criteria:
 - Patient has tried one high-intensity statin therapy (i.e., atorvastatin ≥ 40 mg daily; rosuvastatin ≥ 20 mg daily [as a single entity or as a combination product]; AND
 - Patient has tried one high-intensity statin along with ezetimibe (as a single-entity or as a combination product) for ≥ 8 continuous weeks; AND
 - LDL-C level after this treatment regimen remains ≥ 70 mg/dL; OR

- Patient has been determined to be statin intolerant by meeting one of the following criteria:
 - Patient experienced statin-related rhabdomyolysis (*note: rhabdomyolysis is associated with elevated creatine kinase levels at least 10 times the upper limit of normal, along with evidence of end organ damage which can include signs of acute renal injury [a ≥ 0.5 mg/dL increase in serum creatinine {Scr} levels or doubling of the Scr] and/or myoglobinuria [myoglobin present in urine]; OR*
 - Patient experienced skeletal-related muscle symptoms (*Note: Skeletal-related muscle symptoms include myopathy [muscle weakness] or myalgia [muscle aches, soreness, stiffness, or tenderness]; AND*
 - The skeletal-related muscle symptoms occurred while receiving separate trials of both atorvastatin and rosuvastatin (as a single-entity or as combination products); AND
 - When receiving separate trials of both atorvastatin and rosuvastatin (as a single-entity or as combination products) the skeletal-related muscle symptoms resolved upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin) (*Note: skeletal muscle symptoms include myopathy and myalgia*); AND
- This medication is prescribed by, or in consultation with, a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular risk management and/or lipid disorders.

Approval duration (initial and renewal): 12 months

Dosing Guidelines

284 mg administered as a single subcutaneous injection initially, again at 3 months, and then once every 6 months

References

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11. Jacobson TA, Ito MK, Maki KC, et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: Part 1-full report. *J Clin Lipidol*. 2015;9:129-169. Available at: [http://www.lipidjournal.com/article/S1933-2874\(15\)00059-8/pdf](http://www.lipidjournal.com/article/S1933-2874(15)00059-8/pdf). Accessed on December 29, 2021.