SmartHealth Ascension

Inclisiran

(LEQVIO®) J1306

Covered with prior authorization

Inclisiran (LEQVIO®) may be authorized when the following criteria are met:

Atherosclerotic Cardiovascular Disease [Clinical]

- Individual is ≥ 18 years of age; **AND**
- Individual has had one or more of the following conditions or diagnosis:
  - 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**
  - Individual has undergone a coronary or other arterial revascularization procedure in the past; **AND**

    Note: Example includes coronary artery bypass graft surgery, percutaneous coronary intervention, angioplasty, and coronary stent procedures.
- Individual meets one of the following criteria:
  - Individual has tried one high-density statin therapy (ie., atorvastatin ≥ 40 mg daily; rosuvastatin ≥ 20 mg daily [as single-entity or as a combination product] for ≥ 8 continuous weeks; **AND**
  - Low-density lipoprotein cholesterol level after this treatment remains ≥ 70 mg/dL;

  OR
  - Individual has been determined to be statin intolerant by meeting one of the following criteria:
    - Individual experienced statin-related rhabdomyolysis;
      - Evidence of markedly elevated creatine kinase levels (at least 10 times the upper limit of normal); **AND**
      - 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 increase in Scr or doubling of the Scr] and/or myoglobinuria [myoglobin present in urine]); **OR**
    - Individual meets all of the following criteria:
      - Individual experienced skeletal-related muscle symptoms; **AND**

        Note: Examples of skeletal-related muscle symptoms include myopathy (muscle weakness) or myalgia (muscle aches, soreness, stiffness, or tenderness).
      - The skeletal-related muscle symptoms occurred while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products); **AND**
      - When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the

skeletal-related muscle symptoms resolved upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin); Note: Examples of skeletal-related muscle symptoms include myopathy and myalgia.

AND

- Medication is prescribed by, or in consultation with, a cardiologist; an endocrinologist; or a physician who focuses on the treatment of cardiovascular (CV) risk management and/or lipid disorders; **AND**
- Dose is 284 mg administered as single subcutaneous injection initially, again at 3 months, and then every 6 months.

Heterozygous Familial Hypercholesterolemia (HeFH)

- Individual is ≥ 18 years of age; **AND**
- Individual meets one of the following criteria:
  - Individual has tried one high-density statin therapy (ie., atorvastatin ≥ 40 mg daily; rosuvastatin ≥ 20 mg daily [as single-entity or as a combination product] for ≥ 8 continuous weeks; **AND**
  - LDL-C level after this treatment remains ≥ 70 mg/dL;

  OR
  - Individual has been determined to be statin intolerant by meeting one of the following criteria:
    - Individual experienced statin-related rhabdomyolysis;
      - Evidence of markedly elevated creatine kinase levels (at least 10 times the upper limit of normal); **AND**
      - 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 increase in Scr or doubling of the Scr] and/or myoglobinuria [myoglobin present in urine]); **OR**
    - Individual meets all of the following criteria:
      - Individual experienced skeletal-related muscle symptoms; **AND**
      Note: Examples of skeletal-related muscle symptoms include myopathy (muscle weakness) or myalgia (muscle aches, soreness, stiffness, or tenderness).
    - The skeletal-related muscle symptoms occurred while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products); **AND**
    - When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms resolved upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin); Note: Examples of skeletal-related muscle symptoms include myopathy and myalgia

AND

- Medication is prescribed by, or in consultation with, a cardiologist; an endocrinologist; or a physician who focuses on the treatment of cardiovascular (CV) risk management and/or lipid disorders; **AND**
- Dose is 284 mg administered as single subcutaneous injection initially, again at 3 months, and then every 6 months.

Exclusion criteria:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Concurrent use of LEQVIO® (inclisiran) with Repatha® (evolocumab) or Praluent® (alirocumab) or in combination with lomitapide (Juxtapid®). Repatha® and Praluent® are PCSK9 inhibitors and should not be used with LEQVIO®;
- Pediatric individuals (< 18 years of age);
- Use of PCSK9 inhibitors for individuals with 2 null LDLR pathogenic variants and/or LDL receptor activity less than 2%.

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.
LEQVIO® is a small interfering RNA (siRNA) directed to PCSK9 (proprotein convertase subtilisin kexin type 9) mRNA indicated in adults for the treatment of:

- Adjunct to diet and maximally tolerated statin therapy
- Heterozygous familial hypercholesterolemia (HeFH)
- Clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C)

References:

Leqvio® (inclisiran) label. (2021, December). Accessdata.fda.gov. Retrieved June 19, 2022 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214012lbl.pdf

Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDLCholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways. J Am Coll Cardiol. 2017 Oct 3;70(14):1785-1822.

Grundy SM, Stone NJ, Bailey AL, et al. 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. 2018;000:e1–e120. DOI: 10.1161/CIR.0000000000000625.

Guyton JR, Bays HE, Grundy SM, Jacobson TA. The National Lipid Association Statin Intolerance Panel. An

assessment by the Statin Intolerance Panel: 2014 update. J Clin Lipidol. 2014;8(3 Suppl):S72–81
Raal FJ, Kallend D, Ray KK, et al; ORION-9 Investigators. Inclisiran for the Treatment of Heterozygous Familial Hypercholesterolemia. N Engl J Med. 2020 Apr 16;382(16):1520- 1530. doi: 10.1056/NEJMoa1913805. Epub 2020 Mar 18.
Ray KK, Wright RS, Kallend D, et al; ORION-10 and ORION-11 Investigators. Two Phase 3 Trials of Inclisiran in Patients with Elevated LDL Cholesterol. N Engl J Med. 2020 Apr 16;382(16):1507-1519. doi: 10.1056/NEJMoa1912387. Epub 2020 Mar 18.

Date	Summary of Changes
June 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
July 2022	Criteria for use summary approved by Ascension Cardiovascular Expert Review Panel
July 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.