inclisiran (Leqvio)

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: CARDIOVASCULAR AGENTS
Mechanism of Action: Small interfering RNA (siRNA) directed to PCSK9 mRNA
HCPCS:
J1306:Injection, inclisiran, 1 mg
How Supplied:
284 mg/1.5 mL (189 mg/mL) single-dose prefilled syringe

Condition(s) listed in policy *(see coverage criteria for details)*

- Clinical Atherosclerotic Cardiovascular Disease (ASCVD), Heterozygous Familial Hypercholesterolemia (HeFH), Prevention of CVD Events, or Hypercholesterolemia

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF LEQVIO IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is receiving their first infusion of Leqvio or is being re-initiated on Leqvio after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Leqvio based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Leqvio based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Clinical Atherosclerotic Cardiovascular Disease (ASCVD), Heterozygous Familial Hypercholesterolemia (HeFH), Prevention of CVD Events, or Hypercholesterolemia

Meets medical necessity if all the following are met:

1. Current LDL cholesterol (LDL-C) is at least 70 mg/dl (or at least 55 mg/dl) if extreme risk for heart disease), and one of the following (a, b, or c):
   a. Patient has had at least 8 weeks of treatment with a high-intensity statin
   b. Patient has an FDA-approved package insert (PI) supported contraindication to treatment with all statins
   c. Patient has statin intolerance as evidenced by experiencing one of the following (i, ii, or iii):
      i. Statin-related rhabdomyolysis
      ii. Statin-related skeletal muscle symptoms (e.g., myopathy, myalgia)
      iii. Statin-related elevated hepatic transaminase
2. Inadequate response or intolerable side effect to Praluent (alirocumab) or Repatha (evolocumab), or contraindication to both Praluent and Repatha
3. Dose does not exceed FDA approved maximum

Covered Doses:
Up to 284 mg given as a single subcutaneous injection initially, again at 3 months, and then every 6 months

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:

E78.00, E78.2, E78.5

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Leqvio (inclisiran) [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 7/2025.
4. Handelsman Y, Jellinger PS, Guerin CK, et al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Management of Dyslipidemia and Prevention of Cardiovascular Disease Algorithm - 2020 Executive Summary. *Endocr Pract*. 2020;26(10):1196-1224.
5. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Dyslipidemia and Prevention of Cardiovascular Disease. *Endocr Pract*. 2017;23(Suppl 2):1-87.
6. Gaine S MBBCH, Kulkarni A MD, FACC, Dixon D PharmD, FACC, Patel J MD, FACC. NLA 2022 Definition of Statin Intolerance. American College of Cardiology. Available at: https://www.acc.org/Latest-in-Cardiology/Articles/2022/08/08/12/27/NLA-2022-Definition-of-Statin-Intolerance.
7. Writing Committee; Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2022 Oct 4;80(14):1366-1418. doi: 10.1016/j.jacc.2022.07.006. Epub 2022 Aug 25. Available at: https://www.jacc.org/doi/epdf/10.1016/j.jacc.2022.07.006.
8. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
   Medicare Coverage Database. Available at https://www.cms.gov/Medicare-Coverage-Database/search.aspx
   Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- Clarify coverage to include hypercholesterolemia. Rationale: In July 2025, the FDA expanded approval to use as first-line monotherapy for LDL-C reduction in adults with hypercholesterolemia
- Clarify coverage for statin related intolerance. Rationale: American College of Cardiology NLA 2022 Definition of Statin Intolerance

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee