

inclisiran (Leqvio)

Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

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 request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

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.

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

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- 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, contraindication to Repatha (evolocumab)
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:

one year

Additional Information

Summary of Evidence

The contents of this policy were created after examining the following resources:

1. The prescribing information for Leqvio.
2. The American College of Cardiology (ACC) National Lipid Association (NLA) 2022 Definition of Statin Intolerance.
3. The 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.

Explanation of Rationale:

- Support for FDA-approved indications can be found in the manufacturer's prescribing information.
- Beginning January 1, 2019, the Centers for Medicare & Medicaid Services (CMS) provided Medicare Advantage (MA) plans the option of applying step therapy for physician-administered and other Part B drugs to lower costs and improve the quality of care for Medicare beneficiaries.
- Support for use of Praluent (alirocumab) or Repatha (evolocumab) is found in consensus guidelines. The American College of Cardiology report (Lloyd-Jones et al 2022) includes a stepwise algorithm that recommends PCSK9 monoclonal antibodies (and/or ezetimibe) ahead of Leqvio (or bempedoic acid) [Figure 2c] for adults with clinical ASCVD and baseline LDL-C ≥ 190 mg/dL not due to secondary causes without clinical or genetic diagnosis of familial hypercholesterolemia, on statin therapy for secondary prevention.
- Support for the definitions of statin intolerance is found in the ACC NLA 2022 Definition of Statin Intolerance.

References

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at <https://www.cms.gov/Medicare-Coverage-Database/search.aspx>
3. 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
4. AHFS. Available by subscription at <http://www.lexi.com>

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5. DrugDex. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
6. Leqvio (inclisiran) [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 7/2025.
7. 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.
8. 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.
9. 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>.
10. 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>.
11. 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:

- New policy

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

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