| Inclisiran (Leqvio®) | Place of Service<br>Office Administration<br>Infusion Center Administration<br>Home Infusion Administration<br>Outpatient Facility Administration*<br>[*Prior authorization required – see section (1)]<br><br>HCPCS: J1306 per 1 mg |
|---|---|

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

- Clinical atherosclerotic cardiovascular disease (ASCVD)
- Heterozygous familial hypercholesterolemia (HeFH)
- Primary hyperlipidemia

**AHFS therapeutic class:** Cardiovascular agents

**Mechanism of action**: small interfering RNA (siRNA) directed to PCSK9 mRNA. Catalytic breakdown of mRNA for PCSK9 increases LDL-C receptor recycling and expression on the hepatocyte cell surface, which increases LDL-C uptake and lowers LDL-C levels in the circulation.

## (1) Special Instructions and pertinent Information

**Covered under the medical benefit,** please submit clinical information for prior authorization review via fax.

## (2) Prior Authorization/Medical Review is required for the following condition(s)

**All requests for inclisiran (Leqvio®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

Clinical atherosclerotic cardiovascular disease (ASCVD), Heterozygous familial hypercholesterolemia (HeFH), or Primary hyperlipidemia

1. Inadequate response or intolerable side effect to Praluent (alirocumab) or Repatha (evolocumab), or contraindication to both Praluent and Repatha, **AND**
2. Meets one of the following:
    a. For use with a high-intensity statin (atorvastatin 80 mg, rosuvastatin 40 mg) and current LDL cholesterol (LDL-C) is > 70 mg/dl (or > 55 mg/dl if extreme risk for heart disease) despite 8 weeks of treatment

    **OR**

    b. For use without a high-intensity statin in patients with statin intolerance and one of the following:
        i. Current LDL cholesterol (LDL-C) is > 70 mg/dl (or > 55 mg/dl if provider states extreme risk for heart disease) , and patient has an FDA approved package insert (PI) supported contraindication to treatment with all statins,

        **OR**

        ii. All the following:
            1. Intolerable muscle symptoms which are reversible upon statin discontinuation, but recur upon re-challenge with statin treatment, **and**
            2. Other potential causes of intolerable muscle symptoms have been

maximally managed or ruled out, **and**

3. Trial of at least two different statins (at least one statin is a high-intensity statin such as rosuvastatin or atorvastatin at lowest starting dose)

**Covered Doses**
284 mg SC initially, again at 3 months, and then every 6 months

**Coverage Period**
Indefinite

**ICD-10:**
E78.0, E78.2, E78.5

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**
**All requests for inclisiran (Leqvio®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**(4) This Medication is NOT medically necessary for the following condition(s)**
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**
How supplied:

- 284 mg/1.5 mL (189 mg/mL) single-dose prefilled syringe

| AACE 2017 Atherosclerotic CVD Risk Stratification | | LDL goal |
|---|---|---|
| High risk | ASCVD equivalent including diabetes or stage 3 or 4 CKD with no other risk factors, or individuals with 2 or more risk factors and a 10-year risk of 10%- 20%) | <100 mg/dL |
| Very high risk | Established or recent hospitalization for acute coronary syndrome (ACS); coronary, carotid or peripheral vascular disease; diabetes or stage 3 or 4 CKD with 1 or more risk factors; a calculated 10-year risk greater than 20%; or heterozygous familial hypercholesterolemia [HeFH]) | <70 mg/dL |
| Extreme risk | Progressive ASCVD, including unstable angina that persists after achieving an LDL-C <70 mg/dL, or established clinical ASCVD in individuals with diabetes, stage 3 or 4 CKD, and/or HeFH, or in individuals with a history of premature ASCVD (<55 years of age for males or <65 years of age for females) | <55 mg/dL |

**(6) References**

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Leqvio® (inclisiran) [Prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 12/2021.

## (7) Policy Update

Date of last revision: 4Q2023
Date of next review: 1Q2024
Changes from previous policy version:

- Section (2): Added coverage for treatment of primary hyperlipidemia

  *Rationale: In July 2023, FDA approved Leqvio as adjunctive treatment to reduce LDL-C in adults with primary hyperlipidemia*

- Section (2): Atherosclerotic cardiovascular disease (ASCVD), heterozygous familial hypercholesterolemia (HeFH), prevention of CVD events, or primary hyperlipidemia –
  - Modify adequate trial of high-intensity statin to 8 weeks
  - Removed ezetimibe step therapy requirement

  *Rationale: Consensus guideline support*

*BSC Drug Coverage Criteria to Determine Medical Necessity*
*Reviewed by P&T Committee*