

# Aetna Medicare Part B Drug Step Criteria

## Leqvio (MAPD plans)

### Preferred product(s): Repatha (evolocumab)

This criteria document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization. Step criteria are applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Aetna Medicare Part B Drug Criteria. [Find Aetna Medicare Part B Drug Criteria documents.](#)

This program applies to Leqvio as specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude use of the preferred product and may be based on previous use of a product. The coverage review process will determine situations where a clinical exception can be made. This program applies to all Medicare members who are new to treatment with a targeted product.

**For the indication(s) listed below (new starts only):**

1. Reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

**TABLE. Leqvio**

Status	Product(s)
Preferred*^	Repatha (evolocumab)
Non-preferred (targeted)	Leqvio (inclisiran)

\* The preferred product is available through the Part D benefit and may still require a prior authorization review for medical necessity

^Praluent (alirocumab) is also preferred on open formularies

**EXCEPTION CRITERIA**

Coverage for the targeted product(s) is provided when the member meets one or more of the following criteria:

1. Member has received an authorized dose of the requested product in the past 365 days (does not include samples or doses administered without prior authorization)
2. Documented inadequate response to a trial of the preferred product (documentation required upon request)
3. Documented intolerable adverse event to the preferred product (documentation required upon request)
4. The request is for a medically necessary indication not listed above

**REFERENCES**

1. Leqvio (inclisiran) injection [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2025.
2. Praluent (alirocumab) injection [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; April 2021.
3. Repatha (evolocumab) injection [package insert]. Thousand Oaks, CA: Amgen Inc.; September 2021.



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1015-AMBST

**DOCUMENT HISTORY**

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See Evidence of Coverage for a complete description of plan benefits, exclusions, limitations and conditions of coverage. Plan features and availability may vary by service area.

The formulary may change at any time. You will receive notice when necessary.