VENTURA COUNTY
HEALTH CARE PLAN

CARE VALUE POLICY

POLICY: Proprotein Convertase Subtilisin Kexin Type 9 Related Products Care Value Policy
- Leqvio® (inclisiran subcutaneous injection – Novartis)
- Praluent® (alirocumab subcutaneous injection – Regeneron)
- Repatha® (evolocumab subcutaneous injection – Amgen)

REVIEW DATE: 11/08/2023; selected revision 01/10/2024

OVERVIEW

Praluent and Repatha are proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor antibodies indicated to reduce the risk of various cardiovascular (CV) events (e.g., myocardial infarction, stroke) in adults with established CV disease.[1,2] Both agents are also indicated as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe) for the treatment of primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH]) to reduce low-density lipoprotein cholesterol (LDL-C) in adults. Both agents are also indicated as an adjunctive to other LDL-C lowering therapies for use in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C. For this use, Praluent has only been studied in adults, whereas Repatha has been used in patients as young as 10 years of age. Repatha is also indicated as an adjunct to diet and other LDL-C lowering therapies in pediatric patients ≥ 10 years of age with HeFH, to reduce LDL-C. Leqvio, a small interfering RNA directed to PCSK9 messenger RNA, is indicated as an adjunct to diet and statin therapy for the treatment of primary hyperlipidemia, including HeFH, to reduce LDL-C in adults.[3]

POLICY STATEMENT

This Care Value program has been developed to encourage the use of the Preferred Product. For the Non-Preferred Products, the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The program also directs the patient to try the Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for 1 year.

Automation: None.

Preferred Product: Repatha
Non-Preferred Product: Leqvio, Praluent

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Leqvio	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the *Proprotein Convertase Subtilisin Kexin Type 9 Related Products – Leqvio Prior Authorization Policy* criteria; AND **B)** Patient meets both of the following (i and ii): **i.** Patient has tried Repatha (evolocumab subcutaneous injection); AND **ii.** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber.
Praluent	**1.** Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the *Proprotein Convertase Subtilisin Kexin Type 9 Inhibitors – Praluent Prior Authorization Policy* criteria; AND **B)** Patient meets both of the following (i and ii): **i.** Patient has tried Repatha (evolocumab subcutaneous injection); AND **ii.** Patient has experienced inadequate efficacy or significant intolerance, according to the prescriber.

REFERENCES

1. Praluent® subcutaneous injection [prescribing information]. Tarrytown, NY: Regeneron; April 2021.
2. Repatha® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; September 2021.
3. Leqvio® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; July 2023.