VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

Praluent (alirocumab)

Effective Date 10/27/15
Date Developed 8/24/15 by Catherine R. Sanders, MD
Last Approval Date: 1/24/17, 1/23/18, 1/22/19
(Archived 1/22/19)

Alirocumab is a human monoclonal antibody (IgG1isotype) that binds to proprotein convertase subtilisin kexin type 9 (PCSK9). PCSK9 binds to the low-density lipoprotein receptors (LDLR) on hepatocyte surfaces to promote LDLR degradation within the liver. LDLR is the primary receptor that clears circulating LDL; therefore, the decrease in LDLR levels by PCSK9 results in higher blood levels of LDL-cholesterol (LDL-C). By inhibiting the binding of PCSK9 to LDLR, alirocumab increases the number of LDLRs available to clear LDL, thereby lowering LDL-C levels.

Pharmacologic Category: Antilipemic Agent, PCSK9 Inhibitor

Pre-authorization Criteria:
After review of the available literature, there is no cardiovascular outcome data available. Therefore, the VCHCP P&T Committee has made a decision to designate this medication (and Repatha) as not a covered benefit at this time.
This class of medications should reject at the retail pharmacy or ESI level.

Dosing:
Hyperlipidemia: SubQ 75 mg once every 2 weeks; may increase to 150 mg once every 2 weeks is an adequate response is not achieved within 4-8 weeks.
Missed dose: If a dose is missed ≤7 days from the usual day of administration, administer the dose as soon as possible and then resume the original schedule; otherwise, if beyond 7 dyas, skip the missed dose and resume the normal dosing schedule.

Dosage Forms:
Solution Pen-injector, Subcutaneous [preservative free]
Praluent: 75 mg/mL (1 mL); 150 mg/mL (1 mL)
Solution Prefilled Syringe, Subcutaneous [preservative free]
Praluent: 75 mg/mL (1 mL); 150 mg/mL (1 mL)

Administration:
SubQ: Allow solution to come to room temperature for 30 to 40 minutes prior to administration. Do not shake. Administer by subcutaneous injection into the thigh, abdomen, or upper arm; rotate injection site with each injection. Do not injection into areas of active skin disease or injury (eg, sunburns, skin rashes, inflammation, skin infections). Do not coadminister with other injectable drugs at the same injection site.

Adverse Reactions Significant:
Diarrhea, liver enzyme disorder, increased serum transaminases, hypersensitivity reaction, influenza, injection site reaction, muscle spasm, cough, confusion, memory impairment

Drug Interactions:
Belimumab: Monoclonal Antibodies may enhance the adverse/toxic effect of Belimumab. Risk X: Avoid combination.

REFERENCES:
Praluent (alirocumab) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; July 2015.

Robinson JG, Farnier M, Krempf M, et al. Efficacy and safety of alirocumab in reducing lipids and cardiovascular events. N Engl J Med. 2015;372(16):1489-1499. [PubMed 25773378]
www.uptodate.com: Alirocumab: Drug information 2015

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