

Prior Authorization DRUG Guidelines

**Repatha (evolocumab)**

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)**

Evolocumab 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 Praluent) as not a covered benefit at this time.

This class of medications should reject at the retail pharmacy or ESI level.

**Dosing:**

*Hyperlipidemia: SubQ 140 mg once every 2 weeks; or 420 mg once monthly.*

**Homozygous familial hypercholesterolemia:** 420 mg once monthly

**Dosage Forms:**

*Solution Auto-injector, Subcutaneous [preservative free]*

*Repatha SureClick: 140 mg/mL (1 mL)*

*Solution Prefilled Syringe, Subcutaneous [preservative free]*

*Repatha: 140 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 inject 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:**

*Nasopharyngitis, hypertension, dizziness, gastroenteritis, urinary tract infection, local injection site reaction.*

**Drug Interactions:**

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

**REFERENCES:**

[www.uptodate.com](http://www.uptodate.com): Ecolocumab: Drug information 2015

*Blom DJ, Hala T, Bolognese M, et al; DESCARTES Investigators. A 52-week placebo-controlled trial of evolocumab in hyperlipidemia. N Engl J Med. 2014;370(19):1809-1819.*

**Revision History:**

Date Approved by P&T Committee: 4/26/16

Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/24/17

Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/23/18

Date Reviewed/Archived: 1/22/19 by C. Sanders, MD; R. Sterling, MD

Date Approved by P&T Committee: 1/22/19

| <b>Revision Date</b> | <b>Content Revised (Yes/No)</b> | <b>Contributors</b>                        | <b>Review/Revision Notes</b> |
|----------------------|---------------------------------|--------------------------------------------|------------------------------|
| 1/24/17              | No                              | Catherine Sanders, MD; Robert Sterling, MD | Annual review                |
| 1/23/18              | No                              | Catherine Sanders, MD; Robert Sterling, MD | Annual review                |
| 1/22/19              | No                              | Catherine Sanders, MD; Robert Sterling, MD | Archived – check MCG         |