



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 22, 2015  July 16, 2018

## **REPATHA® (evolocumab)**

**LENGTH OF AUTHORIZATION:** Initial Review: 3 months    Continuation of therapy: 6 months

### **INITIAL REVIEW CRITERIA:**

1. Adult patient age  $\geq$  18 years old with the diagnosis of atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) as confirmed by genotyping or by clinical criteria (“definite FH” using either the Simon Broome or WHO/Dutch Lipid Network criteria).

**OR**

2. Patient age  $\geq$  13 years old with the diagnosis of homozygous familial hypercholesterolemia (HoFH) by either: Documented DNA test for functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality; or a history of an untreated LDL-C concentration  $>$  500 mg/dL and triglycerides  $<$  300 mg/dL and both parents with documented untreated total cholesterol  $>$  250 mg/dL.

**AND**

3. Prior treatment history with highest available dose or maximally-tolerated dose of high intensity statin (e.g. atorvastatin or rosuvastatin) **AND** Zetia for at least three continuous months with failure to reach target LDL-C (70 mg/dL for patients with clinical ASCVD and 100 mg/dL for patients with HeFH or HoFH and no history of clinical ASCVD).
4. If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms. Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all of the following:
  - Muscle symptoms resolve after discontinuation of statin; **AND**
  - Muscle symptoms occurred when re-challenged at a lower dose of the same statin; **AND**
  - Muscle symptoms occurred after switching to an alternative statin; **AND**
  - Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease).

**OR**

5. The patient has been diagnosed with statin-induced rhabdomyolysis.
  - The diagnosis should be supported by acute neuromuscular illness or dark urine **AND** an acute elevation in creatine kinase (usually  $>$ 5,000 IU/L or five times the upper limit of normal).
6. If the patient failed to reach target LDL-C ( $<$ 70 mg/dL for patients with clinical ASCVD and  $<$ 100 mg/dL for patients with HeFH or HoFH and no history of clinical ASCVD), adherence to maximally-tolerated statin and Zetia has been verified using pharmacy claims data and the patient is determined to be compliant for at least three consecutive months prior to the lipid panel demonstrating suboptimal reduction.



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7. Maximally-tolerated statin will continue to be used in conjunction with evolocumab.
  8. Patient has not had a prior trial and failure of an alternative PCSK9 inhibitor.
- OR**
9. Adult patient age  $\geq 18$  years old, for the prevention of cardiovascular events, (myocardial infarction, stroke, and coronary revascularization) with established cardiovascular disease:
    - LDL-C  $\geq 70$ mg/dL and/or non-HDL-C  $\geq 100$ mg/dL; **AND**
    - Prior treatment history with highest available dose or maximally-tolerated dose of high intensity statin (e.g. atorvastatin or rosuvastatin); **AND**
    - Other cardiovascular medication(s) currently in the regimen (e.g. anti-platelet, beta blocker, angiotensin converting enzyme inhibitor, or angiotensin receptor blocker).

#### **CONTINUATION OF THERAPY**

- Lipid panel showing a further reduction in LDL-C compared to the labs prior to initiating evolocumab.
- Continued adherence to maximally-tolerated statin dose established prior to the original evolocumab approval.

#### **DOSING & ADMINISTRATION:**

- Adults with primary hyperlipidemia (including HeFH) or established cardiovascular disease: 140mg subcutaneously every 2 weeks or 420mg subcutaneously once monthly in the abdomen, thigh or upper arm.
- HoFH: 420mg subcutaneously once monthly (3 evolocumab injections consecutively within 30 minutes).