



STATE OF WEST VIRGINIA  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Service  
Prior Authorization Criteria

REPATHA®  
(evolocumab)

[Prior Authorization Request Form](#)

- *Repatha® is a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-cholesterol (LDL-C).*
- *Repatha is also indicated as an adjunct to diet and other LDL-lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.*

**Criteria for Approval**

- 1) Age restrictions are based on diagnosis:
  - a. Patient must be 13 years or older for HoFH **OR**
  - b. 18 years or older for HeFH and ASCVD
- 2) Must be prescribed by or in consultation with a cardiologist or lipid specialist;  
**AND**
- 3) Documentation indicating that treatment with at least two 12-week trials of different high-intensity statins used concomitantly with ezetimibe (Zetia) has been ineffective. Adherence to the current statin regimen must be evidenced by consistent pharmacy claims; **AND**
- 4) The patient will be using Repatha concomitantly with a maximally-tolerated statin or other LDL-lowering therapy; **AND**
- 5) Presence of causal mutation for familial hypercholesterolemia by genetic testing;  
**OR** Definitive clinical evidence supporting the diagnosis of familial hypercholesterolemia (documentation must be provided); **OR**
- 6) The patient must have a documented diagnosis of ASCVD<sup>1</sup> and an LDL of at least 130 mg/dL while on a regimen consisting of a high-intensity statin therapy (at the maximally tolerated dose) in combination with Zetia.



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<sup>1</sup>Diagnosis of ASCVD is defined as one of the following: acute coronary syndrome, or a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin.

**Criteria for Continuation**

- 1) Hypercholesterolemia, ASCVD: Documentation that LDL-C < 100 mg/dL or there has been at least a 40% LDL-C reduction from pre-treatment level; **AND**
- 2) Documentation that the member has been adherent to treatment with statin and PCSK9 inhibitor as demonstrated by consistent pharmacy claims.

**References**

- 1) Repatha package insert revised 9/2015
- 2) Lexi-Comp Clinical Application 02/16/2016
- 3) *Recommendation for the ASCVD LDL cutoff was derived from direct communication with Dr. Joseph Saheen at the 2016 ADURs conference in Scottsdale, AZ.*
- 4) Stone, N. J., Robinson, J., Lichtenstein, A. H., et al. 2013 ACC/AHA Guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *Circulation* 2013. Retrieved from: <http://circ.ahajournals.org>.
- 5) Goldberg, A. C., Hopkins, P. N., Toth, P. P., et al. Familial hypercholesterolemia: Screening, diagnosis and management of pediatric and adult patients. Clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J. of Clinical Lipidology* 2011 Volume 5, Number 3S.



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