



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3066-10
Program	Step Therapy
Medications	Repatha™ (evolocumab)
P&T Approval Date	11/2015, 1/2016, 8/2016, 11/2017, 2/2018, 1/2019, 2/2020, 4/2020
Effective Date	7/1/2020; Oxford only: N/A

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member with a diagnosis of primary hyperlipidemia, heterozygous familial hypercholesterolemia (HeFH) or atherosclerotic cardiovascular disease (ASCVD) that require additional lowering of low density lipoprotein cholesterol (LDL-C) with a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor, to document the trial of maximally tolerated statin therapy prior to the use of Repatha™. Patients with homozygous familial hypercholesterolemia (HoFH) will not be required to meet the Repatha™ step therapy requirements.

Repatha (evolocumab) is a PCSK9 inhibitor antibody indicated to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease, and as an adjunct to diet, alone or in combination with other lipid-lowering therapies, for the treatment of adults with primary hyperlipidemia, including HeFH to reduce LDL-C. Also, it is indicated as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with HoFH who require additional lowering of LDL-C.¹

Members will be required to meet the coverage criteria below. Members, who have received Repatha in the past 60 days as documented in claims history, will be allowed continued coverage of their current therapy.

2. Coverage Criteria^a:

<p>A. Hyperlipidemia</p> <p>1. Repatha will be approved based on all of the following criteria:</p> <p>a. Diagnosis of one of the following:</p> <ul style="list-style-type: none">(1) Primary hyperlipidemia(2) Heterozygous familial hypercholesterolemia(3) Atherosclerotic cardiovascular disease <p style="text-align: center;">-AND-</p>

b. **One** of the following:

- (1) Patient has been receiving at least 12 consecutive weeks of **high-intensity** [i.e. atorvastatin 40-80 mg, Crestor (rosuvastatin) 20-40 mg] statin therapy and will continue to receive high-intensity statin at maximally tolerated dose

-OR-

(2) **Both** of the following:

- (a) Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e. more than 2 weeks) symptoms:
 - i. Myalgia (muscle symptoms without CK elevations)
 - ii. Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN])

-AND-

(b) **One** of the following:

- i. Patient has been receiving at least 12 consecutive weeks of **moderate-intensity** [i.e. atorvastatin 10-20 mg, Crestor (rosuvastatin) 5-10 mg, simvastatin ≥ 20 mg, pravastatin ≥ 40 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) ≥ 2 mg] statin therapy and will continue to receive a moderate-intensity statin at maximally tolerated dose

-OR-

- ii. Patient has been receiving at least 12 weeks of **low-intensity** [i.e. simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] statin therapy and will continue to receive a low-intensity statin at maximally tolerated dose

-OR-

(3) Patient is unable to tolerate **low or moderate, and high-intensity statins** as evidenced by **one** of the following:

- (a) **One** of the following intolerable and persistent (i.e. more than 2 weeks) symptoms for low or moderate, and high-intensity statins:
 - i. Myalgia (muscle symptoms without CK elevations)
 - ii. Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN])

-OR-

(b) Patient has a labeled contraindication to all statins

-OR-

(c) Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN

-AND-

- c. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

Authorization will be issued for 12 months.

B. Other Diagnoses

- 1. Repatha** will be approved

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Medical Necessity, Notification and/or Supply limits may be in place.

4. References:

1. Repatha [package insert]. Thousand Oaks, CA : Amgen Inc. ; February 2019.
2. Lloyd-Jones D, Morris P, Ballantyne C, et al. 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk. *J Am Coll Cardiol.* 2016;68:92-125.
3. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American association of clinical endocrinologists and American college of endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease. *Endocr Pract.* 2017; Suppl 2;23:1-87.
4. Lloyd-Jones D, Morris P, Ballantyne C, et al. 2017 Focused update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk. *J Am Coll Cardiol.* 2017; DOI: 10.1016/j.jacc.2017.07.745.
5. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association



Task Force on Clinical Practice Guidelines. Circulation. 2018; DOI: 10.1161/CIR.0000000000000625.

Program	Step Therapy- Repatha™ (evolocumab)
Change Control	
11/2015	New program.
1/2016	Add statin and Zetia trial criteria along with removal of continuation of therapy criterion.
7/2016	Added Indiana and West Virginia coverage information.
8/2016	Add requirement of Praluent failure at maximum labeled dosing. Updated references.
11/2016	Administrative change. Added California coverage information.
11/2017	Modified previous statin requirement requiring failure, intolerance to high intensity and either moderate or low intensity statin. Removed Zetia trial requirement. Added physician attestation criterion. Updated state mandate verbiage. Updated references.
2/2018	Updated background and coverage criteria to include new indication for patients with primary hyperlipidemia. Updated references.
1/2019	Removed Praluent trial requirement. Updated reference.
2/2020	Annual review with no change to clinical coverage criteria. Updated reference.
4/2020	Updated program to include 60 day claim lookback period for continuation of coverage.