

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 3202-1
Program	Step Therapy
Medication	Lerochol® (lerodalcibep-liga)*
P&T Approval Date	7/2026
Effective Date	10/1/2026

1. Background:

Step Therapy programs are utilized to encourage the 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 and Repatha (evolocumab) prior to the use of Lerochol® (lerodalcibep-liga)*.

Lerochol (lerodalcibep-liga) is a proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor indicated as an adjunct to diet and exercise: to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

2. Coverage Criteria^a:

A. Hyperlipidemia

1. **Lerochol*** will be approved based on **all** of the following criteria:

a. **One** of the following diagnoses:

(1) Primary hyperlipidemia

-OR-

(2) Heterozygous familial hypercholesterolemia (HeFH)

-OR-

(3) Atherosclerotic cardiovascular disease (ASCVD) (e.g., acute coronary syndromes, 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)

-AND-

b. **One** of the following:

(1) Patient has been receiving at least 12 consecutive weeks **of high-intensity statin therapy** [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a 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 creatine kinase (CK) elevations]
 - ii. Myositis [muscle symptoms with CK elevations < 10 times upper limit of normal (ULN)]

-AND-

- (b) Patient has been receiving at least 12 consecutive weeks of low-intensity or moderate-intensity statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin ≥ 10 mg, pravastatin ≥ 10 mg, lovastatin 20-40 mg, fluvastatin XL 80 mg, fluvastatin 20-40 mg up to 40mg twice daily or Livalo (pitavastatin) ≥ 1 mg] and will continue to receive a low-intensity or moderate-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 contraindication to all statins

-OR-

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

-AND-

- c. History of failure, contraindication, or intolerance to Repatha (evolocumab) (document date of trial and list reason for therapeutic failure, contraindication, or intolerance)

Authorization will be issued for 12 months.

B. Other Diagnoses

1. **Lerochol*** 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.

*Lerochol is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

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.

4. **References:**

1. Lerochol [package insert]. Cincinnati, OH: LIB Therapeutics, Inc.; December 2025.
2. Klug EQ, Llerena S, Burgess LJ, et al. Efficacy and Safety of Lerodalcibep in Patients With or at High Risk of Cardiovascular Disease: A Randomized Clinical Trial. *JAMA Cardiol.* 2024;9(9):800–807. doi:10.1001/jamacardio.2024.1659
3. Blumenthal RS, Morris PB, Gaudino M, et al. 2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2026;87(19):2624-2757. doi:10.1016/j.jacc.2025.11.016

Program	Step Therapy - Lerochol [®] (lerodalcibep-liga)*
Change Control	
7/2026	New program.