

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 3056-12
Program	Step Therapy - Statins
Medication	Lescol® XL* (brand and generic fluvastatin extended-release), Livalo®* (brand and generic pitavastatin calcium), Zypitamag®* (pitavastatin magnesium)
P&T Approval Date	7/2015, 7/2016, 9/2017, 10/2018, 10/2019, 10/2020, 11/2021, 12/2022, 1/2024, 3/2025, 3/2026
Effective Date	6/1/2026

1. Background:

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try three alternative statin medications before providing coverage for Lescol XL, Livalo, or Zypitamag.

Members, who have received at least a 90 day supply of Lescol XL, Livalo or Zypitamag in the past 120 days as documented in claims history, will be allowed continued coverage of their current therapy.

2. Coverage Criteria^a:

A. Lescol XL* (fluvastatin extended-release), Livalo (pitavastatin calcium)*, or Zypitamag (pitavastatin magnesium)* will be approved based on the following criterion:

1. History of failure, contraindication or intolerance to **three** of the following:
 - a. atorvastatin (generic Lipitor)
 - b. fluvastatin (generic Lescol)
 - c. lovastatin (generic Mevacor)
 - d. pravastatin (generic Pravachol)
 - e. rosuvastatin (generic Crestor)
 - f. simvastatin (generic Zocor)

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.

*Brand Lescol XL, Livalo, and Zypitamag are typically excluded from coverage. Please refer to plan specifics to determine exclusion status.

3. Additional Clinical Rules:

- Supply limits may apply
- 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. Lescol XL [package insert]. East Hanover, NJ: Novartis Pharmaceutical Corporation; November 2023.
2. Livalo [package insert]. Montgomery, AL: Kowa Pharmaceuticals America, Inc; January 2024.
3. Zypitamag [package insert]. Princeton, NJ: Medicure International, Inc.; December 2024.
4. Grundy et. al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2019 Jun 25;73(24):3168-3209.

Program	Step Therapy – Statins
Change Control	
Date	Change
7/2015	New program.
7/2016	Added rosuvastatin to list of step one medications. Changed authorization to 12 months. Removed comment in background that claims will automatically process based on claims history. Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
9/2017	Updated Livalo to note it is typically excluded. References and state mandate reference language updates.
10/2018	Added Zypitamag to program. Updated references.
10/2019	Annual review. Updated references; added automation language.
10/2020	Annual review. Updated references.
11/2021	Annual review. Updated references.
12/2022	Annual review. Updated references.
1/2024	Annual review. Updated to include generic Livalo. Updated references.
3/2025	Annual review. Updated references.
3/2026	Annual review. No changes.