

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2191-5
Program	Prior Authorization/Medical Necessity - Oxford
Medication/Therapeutic Class	Livalo® (pitavastatin)
P&T Approval Date	3/2020, 6/2021, 6/2022, 10/2023, 10/2024
Effective Date	Oxford: 1/1/2025

1. Background:

Livalo is indicated as an adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia and in adults or pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH).

UnitedHealthcare benefit documents define Therapeutically Equivalent as when medications/products have essentially the same efficacy and adverse effect profile. This determination is made by the UnitedHealthcare Pharmacy and Therapeutics (P&T) Committee and is not intended to imply therapeutic equivalence as defined by the FDA Orange Book.

Oxford plans, due to state mandates, may request a prior authorization for these medications which will require history of failure, contraindication or intolerance to another product(s) or an over-the-counter medication.

2. Coverage Criteria^a:

A. Initial Authorization

1. **Livalo** will be approved based on the following criteria:

a. Submission of medical records documenting history of trial and failure, inadequate response, or intolerance to **three** of the Therapeutically Equivalent covered medications listed below.

- (1) atorvastatin (generic Lipitor)
- (2) fluvastatin (generic Lescol)
- (3) lovastatin (generic Mevacor)
- (4) pravastatin (generic Pravachol)
- (5) rosuvastatin (generic Crestor)
- (6) simvastatin (generic Zocor)

Authorization will be issued for 12 months

B. Reauthorization

1. **Livalo** will be approved based on **both** of the following criteria:

a. Documentation of positive clinical response

-AND-

b. Member is currently on the requested medication as documented in claims history (evidence of claims in past 120 days)

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 Programs:

- Supply limits may also apply.

4. References:

1. Livalo [package insert]. Cincinnati, OH: Kowa Pharmaceuticals America, Inc; March 2024.

Program	Prior Authorization/Medical Necessity - Oxford- Livalo
Change Control	
Date	Change
3/2020	New program
6/2021	Formatting changes. Updated reference.
6/2022	Annual review. No changes.
10/2023	Annual review. Updated reference.
10/2024	Annual review. Added background information. Updated reference.