

Livalo (pitavastatin)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Comment
Livalo (pitavastatin)	Non-Preferred

APPROVAL CRITERIA

Requests for Livalo may be approved when the following criteria are met:

- I. Individual has had a 90 day trial* (medication samples/coupons/discount cards are excluded from consideration as a trial) of two preferred statins and did not achieve LDL cholesterol goal.
 - **Documentation for all cholesterol lowering medications tried and failed MUST be provided:** Should include, but is not limited to, chart notes, prescription claims records, prescription receipts, laboratory data, reason for failure of medications tried (e.g. symptoms, frequency)

Preferred agents: Atorvastatin (generic Lipitor), rosuvastatin (generic Crestor) (does not apply in CA, CO where non-formulary), fluvastatin (generic Lescol) (does not apply in CA, CO where non-formulary), lovastatin (generic Mevacor), pravastatin (generic Pravachol), simvastatin (generic Zocor).

OR

- II. The individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one preferred statin drug at any dose in the previous 180 days and documentation is provided for ONE of the following:
 - A. Diagnosis of rhabdomyolysis; **OR**
 - B. Elevated CPK levels deemed clinically significant by the provider; **OR**
 - Note: A CPK level of 3x the upper normal limits (UNL)
 - Normal CPK: < 200 IU/L
 - C. Elevated LFT levels deemed clinically significant by the provider;
Note: LFTs = ALT or AST levels of 3x the upper normal limits (UNL).
 - Normal ALT (SGPT): < 35 IU/L
 - Normal AST (SGOT): < 35 IU/L

OR

- III. Individual is currently on an agent that interacts with all preferred agents

NOTE: If the individual had elevated CPK or LFTs, they should return to normal limits prior to initiation of therapy with another statin. If the individual had a diagnosis of rhabdomyolysis, clinical symptoms (such as myalgia, generalized weakness, and hemoglobinuria) and CK levels should return to the individual's baseline or deemed appropriate by the provider prior to initiation of therapy with another statin/statin combination.

State Specific Mandates		
<u>State name</u>	<u>Date effective</u>	<u>Mandate details</u> (including specific bill if applicable)
Kentucky	N/A	* Kentucky Health Plan members must only meet the step therapy drug requirement. Members are not subject to the specific length of the drug trial indicated. Kentucky law, SB12-114, requires that step therapy or fail-first protocol shall not be longer than 30 days if the treatment is deemed ineffective by the prescribing provider.

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.