

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Non-Preferred Statins

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Comment
Atorvastatin (generic Lipitor)	Preferred
Lovastatin (generic Mevacor)	
Pravastatin (generic Pravachol)	
Simvastatin (generic Zocor)	
Altoprev (lovastatin XR)	Non-Preferred
Crestor (rosuvastatin)	
Ezallor Sprinkle (rosuvastatin)	
FloLipid (simvastatin)	
Fluvastatin (generic Lescol)	
Fluvastatin ER (generic Lescol XL)	
Lescol (fluvastatin)	
Lescol XL (fluvastatin XL)	
Lipitor (atorvastatin)	
Livalo (pitavastatin)	
Mevacor (lovastatin)	
Pravachol (Pravastatin)	
Rosuvastatin (generic Crestor)	
Zocor (simvastatin)	
Zypitamag (pitavastatin)	

APPROVAL CRITERIA

Requests for a non-preferred statin/statin combination agent may be approved when the following criteria are met:

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply. CRX-ALL-0488-20

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of two preferred statins and did not achieve LDL cholesterol goal.

Preferred agents: atorvastatin, lovastatin, pravastatin, simvastatin.

Non-preferred agents: Altoprev, rosuvastatin (Crestor) – brand and generic, Ezallor Sprinkle, FloLipid, fluvastatin/ER (Lescol/XL) – brand and generic, Lipitor – brand, Livalo, Mevacor – brand, Pravachol – brand, Zocor – brand, Zypitamag.

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 and the individual experienced ONE of the following:

- A. Diagnosis of rhabdomyolysis
- B. Elevated CK levels deemed clinically significant by the provider
Note: A CK level of 3x the upper normal limits (UNL)
➤ Normal CK: < 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 a product that interacts with all the preferred agents;

OR

- IV. Requests for Ezallor Sprinkle (rosuvastatin) may be approved if the following criteria is met:
- A. Individual is unable to swallow the oral tablet dose form due to a clinical condition including but not limited to the following:
 1. Dysphagia.

- V. Requests for a product containing simvastatin 80mg may be approved if the following criteria are met:

- A. For Zocor 80mg brand, in addition to I. or II. or III. above, the individual must also meet the following criteria:
 1. Individual has been on a product containing simvastatin 80 mg for 12 months or more without evidence of muscle toxicity; **OR**
 2. Individual is requesting 80 mg tablets in a quantity consistent with a total daily simvastatin dose of 40mg (example, quantity of 15 for a 30 day supply).
- B. For simvastatin 80mg generic, the individual must meet the following criteria:
 1. Individual has been on a product containing simvastatin 80 mg for 12 months or more without evidence of muscle toxicity; **OR**

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

- Individual is requesting 80 mg tablets in a quantity consistent with a total daily simvastatin dose of 40mg (example, quantity of 15 for a 30 day supply).

NOTE: If the individual experiences elevated CK or LFTs, they should return to the individual's baseline or a level deemed appropriate by the provider prior to initiation of therapy with another statin/statin combination. 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 a level deemed appropriate by the provider prior to initiation of therapy with another statin/statin combination.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

- DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 10, 2019.
- DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 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. *J Am Coll Cardiol*. 2018. <https://doi.org/10.1016/j.jacc.2018.11.003>.
- 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;23(Suppl 2):1-87.
- Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.