Vytorin (ezetimibe/simvastatin)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Vytorin (ezetimibe/simvastatin)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Vytorin (ezetimibe/simvastatin) may be approved when the following criteria are met:

I. Individual has had trial of one preferred high intensity statins, or one statin at maximally tolerated dose and did NOT achieve LDL cholesterol goal (AHA/ACC 2018). Medication samples/coupons/discount cards are excluded from consideration as a trial.

Preferred high intensity statin agents: Atorvastatin (generic Lipitor) 40 mg or 80 mg, rosuvastatin (generic Crestor) 20 mg or 40 mg.

II. Continued Therapy with Vytorin products containing simvastatin 80 mg may be approved when the following criteria are met:

A. Individual has been on a Vytorin product containing simvastatin 80 mg for 12 months or more without evidence of muscle toxicity.

Requests for **brand** Vytorin must also meet the following criteria, in addition to the above Prior Authorization criteria:

I. Individual has failed an adequate trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one chemically equivalent generic ezetimibe/simvastatin agent; **AND**
   A. Generic ezetimibe/simvastatin had inadequate response; **OR**
   B. Generic ezetimibe/simvastatin caused adverse outcome; **OR**
   C. The individual has a genuine allergic reaction an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Key References:

1. Cheeley MK, Saseen JJ, Agarwala A, et. al. NLA scientific statement on statin intolerance: a new definition and key considerations for ASCVD risk reduction in the statin intolerant patient. *J Clin Lipidol*. 2022. https://doi.org/10.1016/j.jacl.2022.05.068.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 15, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. 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: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019;73:e285–350.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.