

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

\*FHK- Florida Healthy Kids

## Zetia (ezetimibe)

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

Medications	Quantity Limit
Zetia (ezetimibe)	May be subject to quantity limit

### APPROVAL CRITERIA

Requests for Zetia (ezetimibe) may be when following criteria are met:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one preferred high intensity statin, or statin therapy at maximally tolerated dose, and did NOT achieve LDL cholesterol goal.
  - Preferred high intensity statin: atorvastatin 40mg, atorvastatin 80mg
- OR**
- II. Individual is statin intolerant, as defined by the National Lipid Association Statin Intolerance Panel and includes the following:
  - A. Inability to tolerate at least 2 statins, with at least one started at the lowest starting daily dose; **AND**
  - B. Statin dose reduction is attempted for symptom and biomarker abnormality resolution, rather than discontinuation of statin therapy altogether; **AND**
  - C. Intolerable symptoms or abnormal biomarker changes are reversible upon statin discontinuation, but reproducible by re-challenge of statins, if clinically appropriate. Statin re-challenge may be appropriate for individuals with all of the following:
    1. Symptomatic; **AND**
    2. Creatine kinase is <4x ULN per laboratory reference range; **AND**
    3. AST/ALT are <3X upper limit of normal, per laboratory reference ranges; **AND**
    4. Symptoms or biomarker abnormalities are not attributable to established predispositions or conditions recognized to increase the risk of statin intolerance, such as:
      - a. Hypothyroidism;
      - b. Drug interactions;
      - c. Concurrent illness;
      - d. Significant changes in physical activity/exercise;
      - e. Underlying muscle disease;

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.

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**OR**

D. Individual has a condition that is a contraindication<sup>^</sup> for statin therapy including active liver disease, unexplained persistent elevation of serum transaminases, or pregnancy, which does not exist for ezetimibe;

**OR**

III. Individual has homozygous familial sitosterolemia

<sup>^</sup>Muscle aches are not considered a contraindication to statin therapy.

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

**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. 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>. Accessed January 30, 2017.

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

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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