Zetia (ezetimibe)

<table>
<thead>
<tr>
<th>Override(s)</th>
<th>Approval Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>1 year</td>
</tr>
<tr>
<td>Quantity Limit</td>
<td></td>
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<table>
<thead>
<tr>
<th>Medications</th>
<th>Quantity Limit</th>
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</thead>
<tbody>
<tr>
<td>Zetia (ezetimibe)</td>
<td>May be subject to quantity limit</td>
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</tbody>
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**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;
### Market Applicability/Effective Date

<table>
<thead>
<tr>
<th>Market</th>
<th>FL &amp; FHK</th>
<th>FL MMA</th>
<th>FL LTC</th>
<th>GA</th>
<th>KS</th>
<th>KY</th>
<th>LA</th>
<th>MD</th>
<th>NJ</th>
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<th>NY</th>
<th>TN</th>
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<th>WA</th>
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<tbody>
<tr>
<td>Applicable</td>
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<td>N/A</td>
<td>X</td>
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*FHK - Florida Healthy Kids

**OR**

D. Individual has a condition that is a contraindication\(^\text{^\text{\textsuperscript{a}}}\) 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 sitosterolemma

\(^\text{\textsuperscript{a}}}\)Muscle aches are not considered a contraindication to statin therapy.

### State Specific Mandates

<table>
<thead>
<tr>
<th>State name</th>
<th>Date effective</th>
<th>Mandate details (including specific bill if applicable)</th>
</tr>
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<tbody>
<tr>
<td>N/A</td>
<td>N/A</td>
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</tbody>
</table>

### Key References:


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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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.