Clinical Pharmacy Program Guidelines for Zetia

<table>
<thead>
<tr>
<th>Program</th>
<th>Prior Authorization</th>
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<tbody>
<tr>
<td>Medication</td>
<td>Zetia (ezetimibe)</td>
</tr>
<tr>
<td>Issue Date</td>
<td>5/2016</td>
</tr>
<tr>
<td>Pharmacy and Therapeutics Approval Date</td>
<td>7/2017</td>
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<tr>
<td>Effective Date</td>
<td>9/2017</td>
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1. **Background:**
   
   **Indications**
   
   **Primary Hypercholesterolemia**
   a. Monotherapy Administered alone, is indicated as adjunctive therapy to diet for the reduction of elevated total-C, LDL-C, Apo B, and non-HDL-C in patients with primary (heterozygous familial and non-familial) hyperlipidemia.
   b. Combination Therapy with HMG-CoA Reductase Inhibitors Administered in combination with an HMG-CoA reductase inhibitor, is indicated as adjunctive therapy to diet for the reduction of elevated total-C, LDL-C, Apo B, and non-HDL-C in patients with primary (heterozygous familial and non-familial) hyperlipidemia.
   c. Combination Therapy with Fenofibrate Administered in combination with fenofibrate, is indicated as adjunctive therapy to diet for the reduction of elevated total-C, LDL-C, Apo B, and non-HDL-C in patients with mixed hyperlipidemia.

   **Homozygous Familial Hypercholesterolemia (HoFH)**
   The combination of Zetia and atorvastatin or simvastatin, is indicated as adjunctive therapy to diet for the reduction of elevated total-C and LDL-C levels in patients with HoFH, as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable.

   **Homozygous Sitosterolemia**
   Zetia is indicated as adjunctive therapy to diet for the reduction of elevated sitosterol and campesterol levels in patients with homozygous familial sitosterolemia.

2. **Coverage Criteria:**

   A. **Zetia**
       1. Zetia will be approved based on **one** of the following criteria:
           a. History of failure, contraindication, or intolerance to one preferred statin [e.g., lovastatin, simvastatin, atorvastatin]
b. Patient with a confirmed diagnosis of homozygous sitosterolemia OR homozygous familial hypercholesterolemia (HoFH)

Authorization will be issued for 12 months.

3. References:


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<tr>
<th>Program</th>
<th>Step Therapy - Zetia (ezetimibe)</th>
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<tr>
<td></td>
<td><strong>Change Control</strong></td>
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<tr>
<td>5/2016</td>
<td>New program</td>
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<tr>
<td>7/2017</td>
<td>Updated policy template. Updated the alternative to a trial of a statin to include a diagnosis of homozygous familial hypercholesterolemia (HoFH)</td>
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