

### Clinical Pharmacy Program Guidelines for Zetia

Program	Prior Authorization
Medication	Zetia (ezetimibe)
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	7/2017
Effective Date	9/2017

**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:**

<p><b>A. Zetia</b></p> <p>1. <b>Zetia</b> will be approved based on <u>one</u> of the following criteria:</p> <p>a. History of failure, contraindication, or intolerance to one preferred statin [eg, lovastatin, simvastatin, atorvastatin]</p>
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**-OR-**

- 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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5. Masana L, Mata P, Gagne C, et al. Long-term safety and, tolerability profiles and lipid-modifying efficacy of ezetimibe coadministered with ongoing simvastatin treatment: a multicenter, randomized, double-blind, placebo-controlled, 48-week extension study. *Clin Ther* 2005;27:174-84.
6. Farnier M, Freeman MW, Macdonell G, et al. Efficacy and safety of the coadministration of ezetimibe with fenofibrate in patients with mixed hyperlipidaemia. *Eur Heart J* 2005 26:897-905.
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11. American Diabetes Association. Dyslipidemia management in adults with diabetes. *Diabetes Care.* 2004 Jan;27(Suppl 1):S68-S71.

12. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk. *J Am Coll Cardiol* Jul 2016; 68 (1): 92-125.
13. Cedo L, Blanco-Vaca F, Escola-Gil JC. Antiatherogenic potential of ezetimibe in sitosterolemia: Beyond plant sterols lowering. *Atherosclerosis* 2017; 260: 94-96.
14. Cannon CP, Blazing MA, Giugliano RP, et al. Ezetimibe Added to Statin Therapy after Acute Coronary Syndromes. *New Engl J Med* 2015; 372 (25): 2387-97.

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