UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Zetia

Program	Prior Authorization
Medication	Zetia (ezetimibe)
Market In Scope	Arizona,California, Colorado, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania CHIP, Rhode Island, South Carolina
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	2/2021

1. Background:

Indications

Primary Hypercholesterolemia

a. Monotherapy: Administered alone, is indicated as adjunctive therapy to diet for the reduction of elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with primary (heterozygous familial and non-familial) hyperlipidemia.

b. Combination Therapy with HMG-CoA Reductase Inhibitors (Statins): Administered in combination with a 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor (statin), 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** will be approved based on one of the following criteria:

1. History of failure, contraindication, or intolerance to one preferred statin [eg, lovastatin, simvastatin, atorvastatin]

-OR-

2. Patient with a confirmed diagnosis of homozygous sitosterolemia OR homozygous familial hypercholesterolemia (HoFH)

Authorization will be issued for 12 months.

3. Additional Clinical Rules

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Zetia [Package insert]. Whitehouse Station, NJ: Merck; November 2019.

Program	Step Therapy - Zetia (ezetimibe)
Change Control	
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)
10/2018	Annual review, minor formatting updates. No changes to clinical intent.
12/2019	Annual Review, updated background.
12/2020	Annual Review, updated reference.