Ezetimibe inhibits absorption of cholesterol at the brush border of the small intestine via the sterol transporter, Niemann-Pick C1-Like1 (NPC1L1). This leads to a decreased delivery of cholesterol to the liver, reduction of hepatic cholesterol stores and an increased clearance of cholesterol from the blood; decreases total cholesterol, LDL cholesterol, apolipoprotein B, and triglycerides while increasing HDL cholesterol.

**Homozygous familial hypercholesterolemia:** In combination with atorvastatin or simvastatin for the reduction of elevated total cholesterol (total-C) and low-density lipoprotein cholesterol (LDL-C) levels in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (eg, LDL apheresis) or if such treatments are unavailable.

**Homozygous sitosterolemia:** As adjunctive therapy to diet for the reduction of elevated sitosterol and campesterol levels in patients with homozygous familial sitosterolemia.

**Primary hyperlipidemia:**

- **Combination therapy with HMG-CoA reductase inhibitors:** In combination with a 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor (statin) as adjunctive therapy to diet for the reduction of elevated total-C, LDL-C, apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with primary (heterozygous familial and nonfamilial) hyperlipidemia.

- **Combination therapy with fenofibrate:** In combination with fenofibrate as adjunctive therapy to diet for the reduction of elevated total-C, LDL-C, apo B, and non-HDL-C in adult patients with mixed hyperlipidemia.

- **Monotherapy:** 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 nonfamilial) hyperlipidemia.

**CRITERIA for APPROVAL:**

Patient had a trial and failure of a generic HMG-CoA reductase inhibitor (Simvastatin, Lovastatin, Pravastatin, etc) or is Ezetimibe being started in combination with an HMG-CoA reductase inhibitor or has had a trial and failure of HMG-CoA reductase inhibitor combination product? Excluding SAMPLES

**REASON for DENIAL of BENEFIT:**

Patient does not meet above criteria

**POLICY HISTORY:**

BENEFIT
APPROVAL: Approval for a two years

References: