

Gateway Health  
Prior Authorization Criteria  
Zetia (Ezetimibe)

All requests for Zetia require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Zetia Prior Authorization Criteria

Coverage may be provided when the members is age 10 years of age or older with a diagnosis of Familial hypercholesterolemia, Mixed hyperlipidemia, Primary hypercholesterolemia, and/or Homozygous Sitosterolemia and the following criteria is met:

- Trial and failure of a minimum of a 6 month trial or an intolerance or contraindication to maximally-tolerated doses of two high-potency statins:
  - a. atorvastatin (Lipitor) 80 mg per day
  - b. rosuvastatin (Crestor) 40 mg per day
- If the member cannot tolerate maximum doses of atorvastatin or Crestor, coverage will be provided if there is documentation of lab work or chart notes confirming the member is intolerant to statin therapy. Intolerance is define by one of the following:
  - a. Liver disease including jaundice, ascites, variceal hemorrhage, hepatic encephalopathy, cholestasis, hepatitis, unexplained elevations in serum aminotransferase
  - b. Laboratory-confirmed rhabdomyolysis resulting from statin treatment. Rhabdomyolysis is defined as myopathy with increase in creatine
  - c. Laboratory-confirmed myopathy resulting from statin treatment. Myopathy is defined as muscle pain with an increase in CPK.
  - d. Elevated CPK
  - e. Women who are pregnant or are actively trying to become pregnant
  - f. Muscle pain, cramping or other hypersensitivity to statin treatment occurring with at least two different statins, one at the lowest starting dose and another at any dose.
- Contraindications
  - a. Active liver disease or unexplained persistent hepatic transaminases, when used with a statin
  - b. Pregnant or nursing mothers, when used with a statin
  - c. Hypersensitivity to ezetimibe or any component of the product

- Initial Benefit: 12 months
- Reauthorization criteria
  - Continued clinical improvements
- For reauthorization: 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.