Prior Authorization Approval Criteria

Welchol (colesevelam)

Generic name: Colesevelam
Brand name: Welchol
Mechanism of action: Bile acid sequestrant
FDA-approved uses: Adjunct to diet and exercise to:
- Reduce elevated low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia as monotherapy or in combination with a hydroxymethyl-glutaryl-coenzyme A (HMG CoA) reductase inhibitor (statin)
- Reduce LDL-C levels in males and postmenarcheal females, 10 to 17 years of age, with heterozygous familial hypercholesterolemia as monotherapy or in combination with a statin after failing an adequate trial of diet therapy
- Improve glycemic control in adults with type 2 diabetes mellitus

Criteria for approval (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records
- Clinically diagnosed with primary hyperlipidemia and:
  - 18 years of age or older
  - Tried/failed or intolerant to cholestyramine andcolestipol
OR
- Clinically diagnosed with heterozygous familial hypercholesterolemia and between the ages of 10 and 17
  - Tried/failed or intolerant to a statin
OR
- Clinically diagnosed with type 2 diabetes mellitus
  - Must have tried/failed or been intolerant to metformin

Criteria for continuation of therapy:
- Patient’s therapy has been re-evaluated within the last 12 months, unless a re-evaluation

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
is not clinically appropriate for the patient’s condition at this time
• Patient is tolerating treatment and there continues to be a medical need for the medication
• Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient’s condition)

Caution:
• May increase triglyceride levels, particularly when used with insulin or sulfonylureas
• Not recommended in patients at risk of bowel obstruction due to its constipating effects
• May decrease absorption of fat-soluble vitamins

Contraindication:
• History of bowel obstruction
• Serum triglyceride (TG) concentrations > 500 mg/dL
• History of hypertriglyceridemia-induced pancreatitis

Approval Duration:
• Indefinite

Benefit Type:
• Pharmacy

Adopted: 6/8/16
Revised: 12/14/16, 3/8/17
Reviewed 3/8/17- added prerequisite drug, continuation of therapy