Cholestyramine Powder

Description

Cholestyramine Powder

Background
Cholestyramine is a binding agent that forms a complex in the intestine with bile acids and facilitates their excretion. This helps decrease the levels of cholesterol as it is a precursor of bile acid. Cholesterol is used to help synthesize new bile acid to make up for the losses resulting in decreased LDL levels. In patients with partial biliary obstruction, excess bile acids are deposited in the skin resulting in pruritus. By decreasing the levels of bile acids, the amount and rate of dermal deposition is decreased (1).

Cholestyramine is commercially available in the following dosage forms: pre-packaged powder and as a loose powder for mixing.

Regulatory Status
FDA approved indication: Adjunct therapy for primary hypercholesterolemia and in pruritus associated with elevated levels of bile acids

The safety and efficacy of cholestyramine have not been established in pregnant women (category C), but cholestyramine has been used in pediatric patients below 2 years of age (1).

Related policies
Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cholestyramine powder may be considered medically necessary for treatment in patients with hypercholesterolemia or in patients dealing with pruritus associated with partial biliary obstruction; and if the conditions indicated below are met.

Cholestyramine powder may be considered investigational for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have ONE of the following:

1. Primary hypercholesterolemia (elevated LDL cholesterol)
   a. Inadequate response to ALL of the following:
      i. Diet and exercise
      ii. High intensity HMG-CoA reductase
      iii. Fibrate
      iv. Niacin (legend)
      v. Zetia

2. Pruritus associated with partial biliary obstruction
   a. Inadequate response to ALL of the following:
      i. Colestipol
      ii. Rifampin
      iii. Opioid antagonist
      iv. Sertraline

   AND ALL of the following:
      a. Inadequate response to the commercially available product
      b. The concentration of the final product doesn’t exceed the maximum recommended daily dose of 24 grams of anhydrous cholestyramine resin
      c. NO history of complete biliary obstruction
Prior – Approval Renewal Requirements
Same as above

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 6 months
* PA is only applicable to cholestyramine bulk powder. All other formulations are excluded from this policy

Prior – Approval Renewal Limits
Same as above

Rationale

Summary
Bile acid sequestrants provide LDL lowering properties by binding to bile acids in the intestine and facilitating their removal. Cholestyramine is FDA approved for the adjunct treatment of hypercholesterolemia as well as pruritic manifestations of partial biliary obstruction. The safety and efficacy have not been established in pregnant women. Cholestyramine is commercially available in the following dosage forms: pre-packaged powder and loose powder.

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of cholestyramine powder while maintaining optimal therapeutic outcomes.

References

2. Cholestyramine In: UpToDate, Waltham, MA, 2019.

Policy History

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September 2019    Annual review and reference update

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.