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5.40.026

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Cardiovascular Agent	**Original Policy Date:**	October 28, 2016
Subject:	Cholestyramine Powder	**Page:**	1 of 4

Last Review Date: March 7, 2025

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 indications: Cholestyramine is indicated: (1-2)

- As adjunctive therapy to diet for primary hypercholesterolemia.
- In pruritus associated with elevated levels of bile acids.

The safety and efficacy of cholestyramine have not been established in pregnant women, 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** 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 treatment response to **ALL** of the following:
        i. Diet and exercise
        ii. High intensity HMG-CoA reductase
        iii. Zetia

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

AND ALL of the following:

a. Inadequate treatment 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

1. Questran [package insert]. Chestnut Ridge, NY: Par Pharmaceutical; November 2019.
2. Cholestyramine In: UpToDate, Waltham, MA, 2022. Accessed on February 2, 2023.

Policy History

Date	Action
October	New addition to PA
March 2017	Annual Review

September 2019	Annual review and reference update
September 2020	Annual review and reference update
March 2021	Annual review
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.40.026. Per SME, removed initiation requirement to t/f fibrate and niacin
March 2024	Annual review
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.