MEDICAL MUTUAL®

Drug Policy

Policy:	**Bile Acid Sequestrants**	**Annual Review Date:** **05/18/2023**
Impacted Drugs:	**Questran, Questran Light, Prevalite (cholestyramine) Colestid (colestipol)**	**Last Revised Date:** **05/18/2023**

OVERVIEW

Bile acid sequestrants are effective agents for the management of primary hypercholesterolemia that work by binding bile acid in the intestine to form an insoluble complex that is fecally secreted without systemic absorption. Three different agents are available in the U.S. Cholestyramine is supplied as a powder for oral suspension, colestipol is available as a powder for oral suspension and in a tablet formulation, and colesevelam is available in a tablet formulation and an oral suspension. Cholestyramine and colestipol (oral suspension packets and tablets) are available generically. The powder formulations must be mixed into a suspension with fluids or with foods. Colestipol and colesevelam are dosed once to twice daily. Cholestyramine is recommended to be given twice daily, but one to six doses per day may be administered.

POLICY STATEMENT

Step therapy rules have been developed to encourage the use of generic bile acid sequestrants prior to a brand name bile acid sequestrants. If the step therapy rule is not met at the point of service, coverage will be determined by the criteria below.

Automation: Patients with a history of one Preferred Medication within the 130-day look-back period are excluded from step therapy.

Preferred Medications

- Generic cholestyramine oral suspension
- Generic colestipol oral suspension and micronized tablets
- Generic colesevelam tablets and packets for oral suspension
- Prevalite oral suspension

Non-Preferred Medication

- Questran oral suspension and light oral suspension
- Colestid oral suspension and micronized tablets

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.

Approval Duration: 365 days (1 year)

Step Therapy Exception Criteria

In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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