STEP THERAPY POLICY

POLICY: Bile Acid Sequestrants Step Therapy Policy

- Questran®, Questran® Light, Prevalite® (cholestyramine oral suspension – Par, Upsher Smith, generic)
- Colestid® (colestipol oral suspension and micronized tablets – Pfizer, generic)
- Welchol® (colesevelam tablets and oral suspension – Cosette, generic)

REVIEW DATE: 06/18/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Cholestyramine is indicated for use as adjunctive therapy for the **lowering of serum cholesterol** in patients with primary hypercholesterolemia who have not responded to diet or other measures alone.[1] Colestipol is indicated as adjunctive therapy to diet for the **reduction of elevated serum total and low-density lipoprotein cholesterol (LDL-C)** in patients with primary hypercholesterolemia (elevated LDL-C) who do not respond adequately to diet.[2,3] Colesevelam is indicated as an adjunct to diet and exercise to **reduce elevated LDL-C** in adults with primary hyperlipidemia as monotherapy or in combination with hydroxymethyl-gutaryl-coenzyme A (HMG CoA) reductase inhibitor (statin).[4]

Colesevelam is also approved to reduce LDL-C levels in boys and postmenarchal girls, aged 10 to 17 years, with heterozygous familial hypercholesterolemia who are unable to reach LDL-C target levels despite an adequate trial of dietary therapy and lifestyle modification. It is approved in this population as monotherapy or as combination therapy with a statin. Colesevelam is also indicated as an adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes mellitus**.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Step 1: cholestyramine oral suspension, colestipol oral suspension, colestipol micronized tablets, colesevelam tablets, colesevelam for oral suspension, Prevalite oral suspension

Step 2: Welchol tablets, Welchol for oral suspension, Questran oral suspension, Questran light oral suspension, Colestid oral suspension, Colestid micronized tablets

Bile Acid Sequestrants Step Therapy Policy **product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.**

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

REFERENCES

1. WelChol® tablets and oral suspension [prescribing information]. South Plainfield, NJ: Cosette; February 2022.
2. Colestid®, Flavored Colestid® oral suspension [prescribing information]. New York, NY: Pfizer; August 2023.
3. Colestid® tablets [prescribing information]. New York, NY: Pfizer; August 2023.
4. Cholestyramine powder, for suspension [prescribing information]. Maple Grove, MN: Upsher-Smith; May 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	06/14/2023

Annual Revision	No criteria changes.	06/26/2024
Annual Revision	No criteria changes.	06/18/2025