LOUISIANA BLUE

Select Ursodiol Products

Policy # 00778
Original Effective Date: 03/14/2022
Current Effective Date: 03/10/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider select ursodiol products, such as Reltone™‡ capsules and ursodiol 200 mg and 400 mg capsules, to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility will be considered for Reltone capsules and ursodiol 200 mg and 400 mg capsules when the following criteria are met:

- Requested drug is being used for one of the following:
  - Dissolution of radiolucent gallbladder stones; OR
  - Gallstone prevention in patients undergoing rapid weight loss; AND
- Patient is 18 years of age or older; AND
- There is clinical evidence or patient history that suggests the use of the GENERIC ursodiol 300 mg capsules will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Reltone capsules and ursodiol 200 mg and 400 mg capsules when there is no clinical evidence or patient history that suggests the use of the GENERIC ursodiol 300 mg capsules will be ineffective or cause an adverse reaction to the patient to be **not medically necessary.****

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Reltone capsules and ursodiol 200 mg and 400 mg capsules when the patient selection criteria are not met (except those denoted as **not medically necessary****) to be **investigational.***

Background/Overview

Reltone capsules, which are available in 200 mg and 400 mg strengths, and ursodiol 200 mg and 400 mg capsules are approved for the dissolution of radiolucent gallbladder stones as well as for gallstone prevention in patients undergoing rapid weight loss. Reltone is considered a branded product, and the ursodiol 200 mg and 400 mg capsules are considered generic products. Other formulations of ursodiol also exist: 300 mg capsules as well as 250 mg and 500 mg tablets. The capsule versions of ursodiol are approved by the FDA for the dissolution of radiolucent gallbladder stones as well as for gallstone prevention in patients undergoing rapid weight loss. The tablet versions of ursodiol are approved by the FDA for primary biliary cholangitis. Reltone and the ursodiol 200 mg and 400 mg capsules have no unique clinical studies as they utilized studies already performed using the 300 mg capsule strength of ursodiol and then extrapolated bioequivalence data. The only strength previously available for the dissolution of radiolucent gallbladder stones as well as for gallstone prevention in patients undergoing rapid weight loss was the 300 mg strength capsule. There can be no claims of superiority of one strength over the other between the capsule strengths. Given that the dosage for gallstone dissolution is 8-10 mg/kg/day in 2-3 divided doses and the dosage for gallstone prevention is 600 mg per day, the 300 mg capsule formulation of ursodiol is more than adequate to meet the needs of patients and has done so for years. There is no clinical reason why Reltone capsules or the 200 mg and 400 mg ursodiol capsules should be used in lieu of the 300 mg ursodiol capsules. The 300 mg ursodiol capsules offer an equally efficacious and more economical option for the dissolution of radiolucent gallbladder stones as well as for gallstone prevention in patients undergoing rapid weight loss.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Reltone capsules and ursodiol 200 mg and 400 mg capsules are both approved for the dissolution of radiolucent gallbladder stones as well as for gallstone prevention in patients undergoing rapid weight loss.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The purpose of this policy is to ensure that Reltone capsules and ursodiol 200 mg and 400 mg capsules are used for their FDA approved indications as well as to ensure that equally efficacious yet more cost effective medications are used for the conditions being treated.

References

1. Reltone [package insert]. Intra-Sana Laboratories LLC. Las Vegas, Nevada. Updated November 2020.
2. Ursodiol 200 mg and 400 mg capsules [package insert]. FH2 Pharm LLC. Updated June 2021.

Policy History

Original Effective Date: 03/14/2022
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02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. New policy.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2025	Medical Policy Committee review
02/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 02/2026

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.