

Drug and Biologic Coverage Policy



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Coverage Policy Number IP0299

Ursodiol

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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. 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.

Overview

This policy supports medical necessity review for the following ursodiol products:

- Reltone (ursodiol 200mg, 400 mg capsules)
- ursodiol 200 mg, 400 mg capsule

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products in below table(s):

Non-Covered Product	Criteria
Reltone™ (ursodiol) 200 mg, 400 mg capsule	Documentation of failure, contraindication, or intolerance to ONE of the following: <ul style="list-style-type: none">• (generic) ursodiol 250 mg tablet• (generic) ursodiol 500 mg tablet

Non-Covered Product	Criteria
ursodiol 200 mg, 400 mg capsule	Documentation of failure, contraindication, or intolerance to ONE of the following: <ul style="list-style-type: none"> • (generic) ursodiol 250 mg tablet • (generic) ursodiol 500 mg tablet

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of ursodiol capsules (Reltone, generics) are considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 12 months.
Reauthorization approval duration is up to 12 months.

Background

OVERVIEW

Ursodiol (ursodesoxycholic acid) is a naturally occurring bile acid found in small quantities in normal human bile and in the bile of certain other mammals.¹

Ursodiol is indicated for patients with radiolucent, noncalcified gallbladder stones < 20 mm in greatest diameter in whom elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to systemic disease, advanced age, idiosyncratic reaction to general anesthesia, or for those patients who refuse surgery. Ursodiol is indicated for the prevention of gallstone formation in obese patients experiencing rapid weight loss.¹

The most widely used treatment for symptomatic gallstones is cholecystectomy.²

References

1. Reltone (ursodiol) [prescribing information]. Las Vegas, NV: Intra-Sana Laboratories LLC; November 2022.
2. Gaby AR. Nutritional approaches to prevention and treatment of gallstones. *Altern Med Rev.* 2009;14(3):258-267.

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