



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

URSODIOL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
URSODIOL	RELTONE, URSODIOL		1073 49115	GPI-14 (52100040000112, 52100040000130)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of radiolucent, noncalcified gallbladder stones and meet **ALL** of the following criteria?
 - The patient's gallbladder stones are less than 20 mm in greatest diameter
 - Elective cholecystectomy is planned unless the patient is at increased surgical risk due to systemic disease, advanced age, or idiosyncratic reaction to general anesthesia, OR the patient refuses surgery
 - The patient had a trial of generic ursodiol (300mg capsule, 250mg tablet, or 500mg tablet)
 - The patient is unable to take generic ursodiol formulations (300mg capsule, 250mg tablet, or 500mg tablet)

If yes, **approve for 12 months by GPID or GPI-14 for the requested strength.**

If no, do not approve.

CLINICAL SPECIALIST NOTE: Use for prevention of gallstone formation in obese patients with rapid weight loss is not covered for this medication.

DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **URSODIOL (Reltone)** requires the following rule(s) be met for approval:

- A. You have radiolucent, noncalcified gallbladder stones (hardened deposits of bile, that is barely visible on x-ray, in your gallbladder that do not contain calcium)
- B. Your gallbladder stones are less than 20 mm in diameter
- C. You plan to have elective cholecystectomy (surgery to remove gallbladder) unless you are at increased surgical risk due to systemic (entire body) disease, advanced age, or idiosyncratic reaction (an unexpected adverse reaction) to general anesthesia, OR you refuse surgery
- D. You have tried generic ursodiol (300mg capsule, 250mg tablet, or 500mg tablet)
- E. You are unable to take generic ursodiol (300mg capsule, 250mg tablet, or 500mg tablet) formulations

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Reltone.

REFERENCES

- Ursodiol 200 mg & 400 mg Capsules [Prescribing Information]. Las Vegas, NV: Intra-Sana Laboratories LLC; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/22

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P&T Approval: 01/21