

# Reltone (ursodiol)

Override(s)	Approval Duration*
Prior Authorization	Initial: 1 year Continuation: 1 year

\*Total approval duration should not exceed 24 months (2 years). The safety and efficacy of Reltone have not been evaluated beyond 2 years of treatment.

Medications
Reltone (ursodiol)

## **APPROVAL CRITERIA**

Requests for Reltone (ursodiol) may be approved if the following criteria are met:

- I. Individual is using for gallstone dissolution; **AND**
- II. Documentation is provided that individual has a well-opacifying gallbladder with radiolucent stones; **AND**
- III. Individual has an increased surgical risk due to systemic disease or advanced age; **AND**
- IV. Individual has had a trial of generically available ursodiol (Actigall), and documentation has been provided for why Reltone (ursodiol) is clinically necessary.

One request for continuation of therapy with Reltone (ursodiol) may be approved if the following criteria are met:

- I. Repeat imaging studies confirm partial dissolution of gallstone(s).

Reltone (ursodiol) may **not** be approved for any of the following:

- I. Individual has calcified (radiopaque) or radiolucent bile pigment stones; **OR**
- II. Individual has calcified cholesterol stones; **OR**
- III. Individual has gallstone complications or compelling reasons for gallbladder surgery (including but not limited to unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary gastrointestinal fistula); **OR**
- IV. Individual is using for the treatment of primary biliary cholangitis.

## **Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 12, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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