

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Chenodal (chenodiol)

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

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

Medications	Quantity Limit
Chenodal (chenodiol) 250mg tablets	May be subject to quantity limit

APPROVAL CRITERIA

Initial Requests for Chenodal (chenodiol) may be approved if the following criteria are met:

- I. Individual is using for gallstone dissolution; **AND**
- II. Individual has a well-opacifying gallbladder with radiolucent stones; **AND**
- III. Individual has an increased surgical risk due to systemic disease or advanced age.

Requests for continuation of therapy with Chenodal (chenodiol) may be approved if the following criteria are met:

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

Chenodal (chenodiol) may **not** be approved for any of the following:

- I. Individual has large or nonfloatable stones; **OR**
- II. Individual has calcified (radiopaque) or radiolucent bile pigment stones; **OR**
- III. Individual has preexisting hepatic impairment; **OR**
- IV. Individual has known hepatocyte dysfunction or bile ductal abnormalities (such as but not limited to intrahepatic cholestasis, primary biliary cirrhosis, or sclerosing cholangitis); **OR**
- V. Individual has a gallbladder confirmed as nonvisualizing after two consecutive single doses of dye; **OR**
- VI. Individual has gallstone complications or compelling reasons for gallbladder surgery (such as but not limited to unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary gastrointestinal fistula).

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Note: Chenodal (chenodiol) is not an appropriate treatment for many patients with gallstones due to the potential for hepatotoxicity, poor response rate in certain subgroups, and increased rate of cholecystectomy needed in other subgroups. Chenodiol should be reserved for carefully selected patients and treatment must be accompanied with liver function monitoring. Chenodiol may cause fetal harm and is contraindicated in women who are or may become pregnant.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: November 21, 2017.

DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.