Commercial/Healthcare Exchange PA Criteria
Effective: May 2017

Prior Authorization: Chenodal

Products Affected: Chenodal (chenodiol) oral tablets

Medication Description:
Chenodiol is a naturally occurring bile acid Chenodal (chenodiol tablets) is indicated for patients with radiolucent stones in well-opacifying gallbladders, in whom elective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age. Chenodal suppresses hepatic synthesis of both cholesterol and cholic acid, gradually replacing cholic acid and its metabolite (deoxycholic acid) in an expanded bile acid pool. This process contributes to biliary cholesterol desaturation and gradual dissolution of radiolucent cholesterol gallstones in the presence of a gallbladder visualized by oral cholecystography. The likelihood of successful dissolution is far greater if the stones are floatable (high cholesterol content) or small. In patients with non-floatable stones, dissolution is less likely and added weight should be given to the risk that more emergent surgery might result from a delay due to unsuccessful treatment.

Covered Uses: Chenodiol is indicated in high surgical-risk adults (due to systemic disease or age) with radiolucent stones in well-opacifying gallbladders.

Exclusion Criteria:
1. Gallstone complications, including need for surgery (e.g., unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary gastrointestinal fistula)
2. Hepatocyte dysfunction or bile ductal abnormalities (e.g., intrahepatic cholestasis, primary biliary cirrhosis, or sclerosing cholangitis)
3. Non-visualizing gallbladder, after 2 consecutive single doses of dye
4. Pregnancy
5. Radiopaque stones

Required Medical Information:
1. Medical history
2. Previous therapies tried and failed
3. Current medication regimen

Age Restrictions: 18 years of age or older

Prescriber Restrictions: N/A

Coverage Duration: 12 months
A. Safety of use beyond 24 months is not established.

Other Criteria:
A. Presence of radiolucent stones in well-opacifying gallbladders; AND
B. Patient is not a candidate for surgery (e.g., due to systemic disease or age); AND
C. Patient has had a trial with or is currently taking an ursodiol product unless contraindicated or clinically significant adverse effects are experienced.

References:

~~1.~~ Chenodal™ tablets [prescribing information]. Fort Collins, CO: Retrophin.™; October 2009.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	05/2017
2	Annual Review	Updated to new template Added Coverage Duration: Safety of use beyond 24 months is not established. Revision Record: 5/18, 5/19	All	04/22/2020