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5.50.030

Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Gastrointestinal Agent	**Original Policy Date:**	May 14, 2021
Subject:	Chenodal	**Page:**	1 of 5

Last Review Date: March 8, 2024

Chenodal

Description

Chenodal (chenodiol)

Background
Chenodiol is the non-proprietary name for chenodeoxycholic acid, a naturally occurring human bile acid. At therapeutic doses, Chenodal (chenodiol) suppresses hepatic synthesis of cholesterol and cholic acid, and inhibit biliary cholesterol secretion, which leads to increased production of cholesterol unsaturated bile thereby allowing for dissolution of gallstones (1-2).

Regulatory Status
FDA-approved indication: Chenodal is indicated for patients with radiolucent stones in well-opacifying gallbladders, in whom selective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age. The likelihood of successful dissolution is far greater if the stones are floatable or small. For patients with nonfloatable 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. Safety of use beyond 24 months is not established. Chenodal will not dissolve calcified (radiopaque) or radiolucent bile pigment stones (2).

If partial dissolution is not seen by 9 to 12 months, the likelihood of success of treating longer is greatly reduced; Chenodal should be discontinued if there is no response by 18 months (2).

Because of the potential hepatoxicity of Chenodal, poor response rate in some subgroups of Chenodal treated patients, and an increased rate of a need for cholecystectomy in other

Chenodal treated subgroups, Chenodal is not an appropriate treatment for many patients with gallstones. Chenodal should be reserved for carefully selected patients and treatment must be accompanied by systematic monitoring for liver function alterations (2).

The optimal frequency of monitoring liver function tests is not known. It is suggested that serum aminotransferase levels should be monitored monthly for the first three months and every three months thereafter during Chenodal administration (2).

Serum cholesterol should be monitored at six months intervals. It may be advisable to discontinue Chenodal if cholesterol rises above the acceptable age-adjusted limit for given patient (2).

Chenodal may cause fetal harm when administered to a pregnant woman. Chenodal is contraindicated in women who are or may become pregnant (2).

The safety and effectiveness of Chenodal in patients less than 18 years of age have not been established (2).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Chenodal may be considered **medically necessary** if the conditions indicated below are met.

Chenodal may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Radiolucent Cholesterol Gallstones

AND ALL of the following:

1. Well-opacifying gallbladder
2. **NO** radiopaque (calcified) or radiolucent bile pigment stones
3. Patient has increased surgical risk due to systemic disease or age
4. Patient has had an inadequate response, intolerance, or contraindication to ursodiol
5. Dose will not exceed 16 mg/kg/day
6. Prescriber agrees to monitor serum cholesterol and liver function tests
7. Female patients of reproductive potential **only**: **NOT** pregnant or planning to become pregnant during treatment with Chenodal

Prior–Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Radiolucent Cholesterol Gallstones

AND ALL of the following:

1. Treatment with Chenodal has not exceeded 24 months
2. Patient has experienced complete dissolution of stones **OR** patient has experienced partial dissolution and prescriber will discontinue therapy if response is not seen by 18 months of treatment
3. Dose will not exceed 16 mg/kg/day
4. Prescriber agrees to monitor serum cholesterol and liver function tests
5. Female patients of reproductive potential **only**: **NOT** pregnant or planning to become pregnant during treatment with Chenodal

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Duration 12 months

Prior–Approval *Renewal* Limits

Duration 12 months **(ONE renewal ONLY)**

Rationale

Summary
Chenodal (chenodiol) is indicated for patients with radiolucent stones in well-opacifying gallbladders, in whom selective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age. The likelihood of successful dissolution is far greater if the stones are floatable or small. For patients with nonfloatable 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. Safety of use beyond 24 months is not established. Chenodal will not dissolve calcified (radiopaque) or radiolucent bile pigment stones. Chenodal may cause fetal harm when administered to a pregnant woman. Chenodal is contraindicated in women who are or may become pregnant. The safety and effectiveness of Chenodal in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Chenodal while maintaining optimal therapeutic outcomes.

References

1. Chenodal. Drug Facts and Comparisons. eFacts [online]. 2021. Available from Wolters Kluwer Health, Inc.
2. Chenodal [package insert]. San Diego, CA. Travere Therapeutics; July 2023.

Policy History

Date	Action

May 2021	Addition to PA
September 2021	Annual review and reference update
March 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.50.030
June 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.