CHENODIOL

Generic	Brand	HICL	GCN	Exception/Other
CHENODIOL	CHENODAL	01364		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the requested medication being prescribed for the treatment of cerebrotendinous xanthomatosis (CTX)?

   If yes, **approve for 12 months by HICL with a quantity limit of #3 tablets daily.**
   If no, continue to #2.

2. Is the requested medication being prescribed for the treatment of radiolucent gallstones?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Has the patient received previous chenodiol therapy with a total duration exceeding 24 months?

   If yes, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.
   If no, continue to #4.

4. Has the patient had a previous trial of or contraindication to ursodiol?

   If yes, **approve for 12 months by HICL with a quantity limit of #7 tablets daily.**
   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **CHENODIOL (Chenodal)** requires a diagnosis of radiolucent gallstones or cerebrotendinous xanthomatosis. The following criteria must also be met:
   For the diagnosis of radiolucent gallstones:
   - The patient has had a previous trial of or contraindication to ursodiol
   - The patient has not received previous chenodiol therapy with a total duration exceeding 24 months

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CHENODIOL

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Is the requested medication being used for radiolucent gallstones?

   If yes, continue to #2.
   If no, continue to #5.

2. Has the patient previously received a total duration of chenodiol therapy exceeding 24 months?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #3.

3. Does the patient have complete or no gallstone dissolution seen on imaging after 12 months of therapy?

   If yes, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.
   If no, continue to #4.

4. Does the patient have partial gallstone dissolution seen on imaging after 12 months of therapy?

   If yes, **approve for 12 months by HICL with a quantity limit of #7 tablets daily.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

5. Does the patient have a diagnosis of cerebrotendinous xanthomatosis (CTX) **AND** meet the following criterion?
   - Physician attestation of improvement in **ONE** of the following:
     - Normalization of elevated serum or urine bile alcohols
     - Normalization of elevated serum cholestanol levels
     - Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

   If yes, **approve for 12 months by HICL with a quantity limit of #3 tablets daily.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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CHENODIOL

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline for **CHENODIOL (Chenodal)** requires a diagnosis of radiolucent gallstones or cerebrotendinous xanthomatosis. The following criteria must also be met:

For the diagnosis of radiolucent gallstones:

- The patient has **NOT** exceeded a total of 24 months of previous chenodiol therapy
- The patient does **NOT** have complete or no gallstone dissolution seen on imaging (e.g., oral cholecystograms or ultrasonograms) after 12 months of therapy
- The patient has partial gallstone dissolution seen on imaging (e.g., oral cholecystograms or ultrasonograms) after 12 months of therapy

For the diagnosis of cerebrotendinous xanthomatosis:

- Physician attestation of improvement in **ONE** of the following:
  - Normalization of elevated serum or urine bile alcohols
  - Normalization of elevated serum cholestanol levels
  - Improvement in neurologic and psychiatric symptoms (dementia, pyramidal tract and cerebellar signs)

RATIONALE

Ensure appropriate utilization for chenodiol.

FDA APPROVED INDICATIONS

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. Chenodiol will not dissolve calcified (radiopaque) or radiolucent bile pigment stones.

Because of the potential hepatoxicity of chenodiol, poor response rate in some subgroups of chenodiol-treated patients, and an increased rate of a need for cholecystectomy in other chenodiol-treated subgroups, chenodiol is not an appropriate treatment for many patients with gallstones. Chenodiol should be reserved for carefully selected patients and treatment must be accompanied by systematic monitoring for liver function alterations. Aspects of patient selection, response rates and risks versus benefits are given in the package insert.

Chenodiol is used off-label for the treatment of cerebrotendinous xanthomatosis.

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CHENODIOL

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

Radiolucent gallstones:

The recommended dose range for chenodiol is 13 to 16mg/kg/day in two divided doses, morning and night. Starting with 250 mg two times a day for the first two weeks and increasing by 250 mg/day each week thereafter until the recommended or maximum tolerated dose is reached. If diarrhea occurs during dosage buildup or later in treatment, it usually can be controlled by temporary dosage adjustment until symptoms abate, after which the previous dosage usually is tolerated. Dosage less than 10 mg/kg usually is ineffective and may be associated with increased risk of cholecystectomy, so is not recommended.

Cerebrotendinous xanthomatosis:

The recommended dose for chenodiol for adults is 250 mg three times a day and 15 mg/kg per day in three divided doses for children.

REFERENCES

- Chenodal [Prescribing Information]. Manchester Pharmaceuticals, Inc. Fort Collins, CO. Sept 2009.
- Ransohoff DF, Gracie WA. Guidelines for the Treatment of Gallstones. *Ann Intern Med*. 1993; 119:620-622.
- UpToDate, Inc. Cerebrotendinous xanthomatosis. UpToDate [database online]. Last updated Dec 20, 2016.
- UpToDate, Inc. Nonsurgical treatment of gallstones. UpToDate [database online]. Last updated Mar 6, 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/18
Created: 11/09
Client Approval: 09/18
P&T Approval: 07/18