Reference number(s)
4350-A

SPECIALTY GUIDELINE MANAGEMENT

CHENODAL (chenodiol)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

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.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Chart notes to support an inadequate treatment response or an intolerance to ursodiol

III. CRITERIA FOR INITIAL APPROVAL

Radiolucent stones in well-opacifying gallbladders
[Note: Chenodal will not dissolve calcified (radiopaque) or radiolucent bile pigment stones.]
Authorization of 12 months may be granted for treatment of members with radiolucent stones in well-opacifying gallbladders when all of the following criteria are met:
A. Member has an increased surgical risk due to systemic disease or age.
B. Member experienced an inadequate treatment response or intolerance to ursodiol.
C. Member will not exceed a dose of 16 mg/kg/day. Member's current weight must be provided.

IV. CONTINUATION OF THERAPY

Radiolucent stones in well-opacifying gallbladders
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when all of the following criteria are met:
A. Patient has experienced partial (or complete) dissolution of stones, or patient has not experienced a partial dissolution and provider will discontinue therapy with the requested drug if response is not seen by 18 months of treatment.
B. There is no evidence of unacceptable toxicity.
C. Member will not exceed a dose of 16 mg/kg/day. Member's current weight must be provided.

V. REFERENCES

1. Chenodal [package insert]. San Diego, CA: Retrophin, Inc.; December 2020.
2. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ (cited: November 23, 2020).
3. Ursodiol [package insert]. Irvine, CA: Nexgen Pharma, Inc.; August 2020.