MEDICAL MUTUAL®

Drug Policy

Policy:	Chenodiol Products Prior Authorization Policy • **Chenodal™ (chenodiol tablets – Travere)** • **Ctexli™ (chenodiol tablets – Mirum)**	**Annual Review Date:** 03/19/2026 **Last Revised Date:** 03/19/2026

OVERVIEW

Chenodiol products are naturally occurring bile acids. **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.[1] **Ctexli** is indicated for the treatment of of **cerebrotendinous xanthomatosis** in adults.[2]

POLICY STATEMENT

This policy involves the use of Chenodiol Products. Prior authorization is recommended for pharmacy benefit coverage of Chenodiol Products. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Chenodiol Products as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Chenodiol Products be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of **Chenodal** is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Gallstones.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Patient has tried an ursodiol product*; OR
   - **B)** Patient is currently receiving an ursodiol product.

II. Coverage of **Ctexli** is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Cerebrotendinous Xanthomatosis.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** The diagnosis is established by ONE of the following* (i or ii):
     - **i.** Patient has a molecular genetic test demonstrating a pathogenic variant in the cytochrome P450 27A1 *(CYP27A1)* gene; OR
     - **ii.** Patient has a laboratory test demonstrating elevated serum cholestanol levels; AND
   - **B)** The medication is prescribed by or in consultation with a geneticist, neurologist, ophthalmologist, metabolic specialist who treats patients with cerebrotendinous xanthomatosis or a specialist who focuses in the treatment of cerebrotendinous xanthomatosis.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Chenodiol Products have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Combination Therapy with Cholbam (cholic acid capsules)**. There are no efficacy data available to support concomitant use.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

***Documentation Requirements:**
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Chenodal™ tablets [prescribing information]. San Diego, CA: Travere; May 2021.
2. Ctexli™ tablets [prescribing information]. Foster City, CA: Mirum; December 2025.
3. Gaby AR. Nutritional approaches to prevention and treatment of gallstones. *Altern Med Rev.* 2009;14(3):258-267.
4. Abraham S, Rivero HG, Erlikh IV, Griffith LF, and Hondamudi VK. Surgical and nonsurgical management of gallstones. *Am Fam Physician*. 2014;89(10):795-802.
5. Moghadasian MH, Salen G, Frohlich JJ, et al. Cerebrotendinous xanthomatosis. *Arch Neurol*. 2002;59:527-529.
6. Lorincz MT, Rainier S, Thomas D and Fink JK. Cerebrotendinous xanthomatosis: possible higher prevalence than previously recognized. *Arch Neurol.* 2005;62:1459-1463.

7. Stelten B, Dotti M., Verrips A, et al. Expert opinion on diagnosing, treating and managing patients with cerebrotendinous xanthomatosis (CTX): a modified Delphi study. *Orphanet J Rare Dis* 16, 353 (2021). Available at: https://doi.org/10.1186/s13023-021-01980-5. Accessed on: February 25, 2026.