PRIOR AUTHORIZATION POLICY

POLICY: Chenodal Prior Authorization Policy
- Chenodal™ (chenodiol tablets – Travere)

REVIEW DATE: 08/28/2024

OVERVIEW

Chenodal, a naturally occurring bile acid, 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]

The most widely used treatment for symptomatic gallstones is cholecystectomy.[2] Two naturally occurring bile acids are used in the treatment of gallstones: ursodeoxycholic acid (UrsoForte®, Urso-250®, [ursodiol tablets, generic], Actigall® [ursodiol capsules, generic]) and chenodeoxycholic acid/chenodiol (Chenodal).[3] These agents reduce biliary cholesterol; however, their exact mechanisms differ. Both Chenodal and ursodiol promote the gradual dissolution of radiolucent gallstones over a period of 6 months to 2 years.[2]

Other Uses with Supportive Evidence

Cerebrotendinous xanthomatosis (CTX) is a lipid storage disorder with various clinical manifestations including juvenile cataracts, tendon xanthomas, premature atherosclerosis, and progressive neurologic disturbance (e.g., ataxia, seizures, psychiatric disorders, and peripheral neuropathy).[4] Other conditions associated with CTX include osteoarthritis, skeletal fractures, pulmonary insufficiency, renal and hepatic calculi, and childhood chronic diarrhea. CTX is the result of a mutated enzyme (cytochrome P450 27-sterol hydroxylase) which is normally responsible for the conversion of cholesterol to cholic acid and chenodeoxycholic acid. In CTX, reduced synthesis of cholic and chenodeoxycholic acids results in failed feedback inhibition of cholesterol production, in turn leading to hallmark laboratory findings of the disorder: increased serum cholesterol concentrations and elevated urinary bile alcohols.[5] Replacement therapy with chenodiol inhibits abnormal bile acid synthesis and is most effective in reducing elevated plasma cholesterol concentrations and eliminating bile alcohols.[4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Chenodal. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Chenodal as well as the monitoring required for adverse events and long-term efficacy, approval requires Chenodal to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Chenodal is recommended in those who meet one of 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.

Other Uses with Supportive Evidence

2. **Cerebrotendinous Xanthomatosis.** Approve for 1 year if Chenodal is prescribed by or in consultation with a metabolic specialist who treats patients with cerebrotendinous xanthomatosis or a specialist who focuses in the treatment of cerebrotendinous xanthomatosis.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Chenodal is not recommended in the following situations:

1. **Combination Therapy with Cholbam (cholic acid capsules)**. There are no efficacy data available to support use of combination therapy with Chenodal and Cholbam.

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

REFERENCES

1. Chenodal™ tablets [prescribing information]. San Diego, CA: Travere; May 2021.
2. Gaby AR. Nutritional approaches to prevention and treatment of gallstones. *Altern Med Rev.* 2009;14(3):258-267.
3. 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.
4. Moghadasian MH, Salen G, Frohlich JJ, et al. Cerebrotendinous xanthomatosis. *Arch Neurol.* 2002;59:527-529.
5. Lorincz MT, Rainier S, Thomas D and Fink JK. Cerebrotendinous xanthomatosis: possible higher prevalence than previously recognized. *Arch Neurol.* 2005;62:1459-1463.