Pharmacy Drug Policy & Procedure

Policy Name:	Chenodal (chenodiol)	Policy#:	3235P

Purpose of the Policy

The purpose of this policy is to define coverage criteria for Chenodal (chenodiol).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Chenodal (chenodiol) under the specialty pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria for Gallstone Dissolution

1.1 Documented diagnosis of radiolucent gallstones in well-opacifying gallbladders
- Documentation to support stones are not calcified (radiopaque) or radiolucent bile pigment stones

1.2 Patient is not a candidate for surgery

1.3 Prescribed by or in consultation with a gastroenterologist (stomach doctor)

1.4 Previous trial and failure, intolerance or contraindication to ursodiol

2. Coverage Criteria for Cerebrotendinous Xanthomatosis (CTX)

2.1 Diagnosis of cerebrotendinous xanthomatosis as confirmed by genetic testing with evidence of pathogenic CYP27A1 variants

2.2 Prescribed by or in consultation with a metabolic specialist (metabolism doctor)

3. Exclusion Criteria

3.1 Pregnancy

3.2 Liver dysfunction, bile duct abnormalities, non-visualizing gallbladder after 2 single doses of dye, gallstone complications requiring surgery

4. Managed Dose Limit

4.1 #90 tablets per 30 days
- Requests for exceeding this quantity require documentation of patient weight to support weight based dosing that exceeds this quantity limit

5. Approval Period

5.1 Initial: 12 months

5.2 Reauthorization: 12 months with documentation patient's condition warrants continued treatment and benefit from therapy
- For Gallstone Dissolution indication: maximum duration of therapy is 24 months (safety of use beyond 24 months has not been established for this indication)

CPT Codes	

HCPCS Codes

References

1. Chenodal (chenodiol) [prescribing information]. San Diego, CA: Travere Therapeutics; May 2021.
2. Fromm H, Malavolti M. Bile acid dissolution therapy of gallbladder stones. Baillieres Clin Gastroenterol 1992; 6:689.
3. Yahalom G, Tsabari R, Molshatzki N, et al. Neurological outcome in cerebrotendinous xanthomatosis treated with chenodeoxycholic acid: early versus late diagnosis. Clin Neuropharmacol 2013; 36:78.
4. Federico A, Gallus GN. Cerebrotendinous Xanthomatosis. 2003 Jul 16 [updated 2022 Mar 17]. In: Adam MP, Feldman J, Mirzaa GM, et al, editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993–2024.

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