



## Pharmacy Drug Policy & Procedure

<b>Policy Name:</b>	<b>Cholbam (cholic acid)</b>	<b>Policy#:</b>	<b>2345P</b>
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### Purpose of the Policy

The purpose of this policy is to define coverage criteria for Cholbam (cholic acid)

### Statement of the Policy

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

### Criteria

#### 1. Coverage Criteria

- 1.1 Ordered by a Hepatologist (liver doctor) or Pediatric Gastroenterologist (stomach doctor for kids)
- 1.2 Age 3 weeks or older
- 1.3 Documented diagnosis of ONE of the following:
  - Documented diagnosis of bile acid disorder due to defects in required enzymes
  - Documented diagnosis of peroxisomal disorder (including Zellweger spectrum disorder) and documentation of manifestations of liver disease, steatorrhea (fat in stool), or complications from decreased fat soluble vitamin absorption

#### 2. Exclusion Criteria

- 2.1 Cholbam is not covered for the treatment of extrahepatic manifestations of bile acid synthesis disorders due to single enzyme defects or because the safety and effectiveness have not yet been established

#### 3. Approval Period

- 3.1 Initial approval period: 12 months
- 3.2 Reapproval period: 12 months

### CPT Codes

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### HCPCS Codes

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### References

1. Cholbam (cholic acid) [prescribing information]. San Diego, CA: Manchester Pharmaceuticals Inc; March 2023.
2. Setchell KD, Heubi JE. Defects in bile acid biosynthesis--diagnosis and treatment. J Pediatr Gastroenterol Nutr 2006; 43 Suppl 1:S17.
3. Klouwer FCC, Koot BGP, Berendse K, et al. The cholic acid extension study in Zellweger spectrum

disorders: results and implications for therapy. J Inherit Metab Dis. 2019;42(2):303-312.

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#### DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.