



Pharmacy Policy

Cholbam

Policy Number: 9.308

Revision Number: R0

Version Effective Date: 01/1/2021

Product Applicability All Plan+ Products

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth - MCO

MassHealth - ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Cholbam (cholic acid)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	Documentation of all the following: 1. One of the following: a. Diagnosis of bile acid synthesis disorders due to single enzyme defects (SEDs); OR b. Diagnosis of peroxisomal disorders (PDs) including Zellweger Spectrum Disorders; AND Member has manifestations of liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption; AND 2. Diagnosis has been confirmed by genetic testing and/or liver biopsy (<i>medical records confirming diagnosis must be provided</i>)

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Age Restriction	None
Prescriber Restriction	Medication is prescribed by or in collaboration with a hepatologist, metabolic specialist, or gastroenterologist
Coverage Duration	Initial: 3 months Re-authorization: 12 months
Other criteria	<p>Re-authorization:</p> <ol style="list-style-type: none"> 1. Lab findings confirming there has been an improvement in ALT or AST values from baseline (lab values must be provided); AND 2. Weight has improved from baseline; AND 3. Member does not have complete biliary obstruction <p>Note: Treatment will be discontinued after initial 3 months if there is no improvement seen in clinical status.</p>

Clinical Background Information and References

1. Cholbam™ [package insert]. Baltimore, MD: Askleion Pharmaceuticals, LLC; March 2015.
2. Percy AK, Wanders JA. Peroxisomal disorders. UpToDate. Accessed February 19, 2016.
3. Erlichman J, Loomes KM. Causes of cholestasis in neonates and young infants. UpToDate. Last updated Jul 24, 2018. Accessed February 12, 2019.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	P&T Committee, NH DHHS

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.062 Cholbam Policy retired and created new policy per line of business where applicable..	1/12021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

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Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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