BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Cholbam

Policy Number: 9.308
Version Number: 2.0
Version Effective Date: 3/1/2022

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	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** i. 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 *(medical records confirming diagnosis must be provided)*

⁺ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Age Restriction	None
Prescriber Restriction	Medication is prescribed by or in collaboration with a hepatologist, metabolic disease specialist, or gastroenterologist
Coverage Duration	Initial: 3 months Re-authorization: 12 months
Other criteria	Re-authorization: 1. Lab findings confirm 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 Note: Treatment will be discontinued after initial 3 months if there is no improvement seen in clinical status.

Clinical Background Information and References

1. Cholbam™ [package insert]. Baltimore, MD: Asklepion Pharmaceuticals, LLC; December 2020.
2. Wanders JA. Peroxisomal disorders. UpToDate. Last updated March 3, 2020. Accessed October 2021.
3. Erlichman J, Loomes KM. Causes of cholestasis in neonates and young infants. UptoDate. Last updated January 29, 2021. Accessed October 2021.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.062 Cholbam Policy retired, new policy created	1/1/2021	P&T Committee
11/11/2021	P&T annual review. Minor rewording for clarity.	3/1/2022	P&T Committee

Next Review Date

11/ 2022

Other Applicable Policies

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.