

Pharmacy Policy

Ocaliva[®] (obeticholic acid)

Policy Number: 9.803

Revision Number: R0

Version Effective Date: 1/1/2021

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:

- Ocaliva[®] (miltefosine)

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	<ol style="list-style-type: none"> 1. Diagnosis of primary biliary cholangitis established by or in consultation with gastroenterologist or hepatologist; AND 2. Laboratory values documenting alkaline phosphatase levels greater than or equal to 1.6 times the upper limit of normal prior to treatment initiation; AND 3. An inadequate response to ursodeoxycholic acid/ursodiol as monotherapy and Ocaliva will be used in combination with ursodeoxycholic acid/ursodiol; OR <p>An intolerance or contraindication to ursodeoxycholic acid/ursodiol;</p>

* 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	18 years or older
Prescriber Restriction	None
Coverage Duration	Initial: Maximum of 6 months Reauthorization: Maximum of 12 months
Other criteria	1. Clinical response to Ocaliva® therapy as evidenced by laboratory values documenting a reduction in alkaline phosphatase levels from baseline without adverse events.

Clinical Background Information and References

- Ocaliva® (obeticholic acid) [prescribing information]. New York, NY: Intercept Pharmaceuticals, Inc.; May 2016.

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

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.070 Ocaliva Policy retired, new policy created	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

N/A

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

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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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