BOSTON MEDICAL CENTER HEALTHNet PLAN

bmchp.org | 888-566-0008

Pharmacy Policy

Ocaliva®

Policy Number: 9.803
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:

- **Ocaliva® (obeticholic 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
Required Medical Information	1. Diagnosis of primary biliary cholangitis (PBC); ***AND*** 2. Documentation of laboratory values indicating alkaline phosphatase levels greater than or equal to 1.6 times the upper limit of normal prior to treatment initiation; ***AND*** 3. One of the following

+ *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.

	a. The member has had an inadequate response to at least 1 year of therapy with ursodiol and Ocaliva will be used in combination with ursodiol; ***OR*** b. The member has an intolerance or contraindication to ursodiol
Age Restriction	18 years or older
Prescriber Restriction	Prescribed by or in consultation with a hepatologist or gastroenterologist
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Other criteria	**Reauthorization:** 1. Diagnosis of primary biliary cholangitis (PBC) ; ***AND*** 2. One of the following a. The member has had an inadequate response to at least 1 year of therapy with ursodiol and Ocaliva will be used in combination with ursodiol; ***OR*** b. The member has an intolerance or contraindication to ursodiol; ***AND*** 3. Documentation that the member is responding positively to therapy as evidenced by a reduction in alkaline phosphatase levels from pretreatment levels 4.

Clinical Background Information and References

1. Ocaliva® (obeticholic acid) [prescribing information]. New York, NY: Intercept Pharmaceuticals, Inc.; June 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	9.070 Ocaliva Policy retired, new policy created	1/1/2021	P&T Committee
11/11/2021	P&T Annual Review. Slight adjustment to initial criteria. Added more robust reauthorization criteria.	3/1/2022	P&T Committee

Next Review Date

11/2022

Other Applicable Policies

N/A

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.