JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS109
		Effective Date	10/18/2017
		Review Date	01/19/2022
	Subject **Ocaliva**	*Revision Date*	01/19/2022
		Page	1 of 2

This document applies to the following Participating Organizations:

Priority Partners

Keywords: Ocaliva

Table of Contents		Page Number
I.	POLICY	1
II.	POLICY CRITERIA	1
III.	AUTHORIZATION PERIOD/LIMITATIONS	1
IV.	EXCLUSIONS	1
V.	REFERENCES	2
VI.	APPROVALS	2

I. POLICY

A. Ocaliva (obeticholic acid) will require prior authorization to ensure appropriate use. It will require prior authorization for outpatient prescription drug benefit coverage to ensure this medication is used only when clinically appropriate. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare PolicyManual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Ocaliva may be approved for patients meeting the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing a diagnosis of primary biliary cholangitis (PBC)
   3. Documentation has been submitted showing one of the following:
      a. Patient does not have cirrhosis
      b. Patient has compensated cirrhosis without evidence of portal hypertension
   4. Ocaliva is being used in conjunction with ursodeoxycholic acid (UDCA) or as monotherapy in patients with documented inadequate response to ursodeoxycholic acid

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with clinical documentation demonstrating clinical benefit from treatment

IV. EXCLUSIONS

A. Ocaliva will not be approved for the following:
   1. Patient with any of the following:
      a. decompensated cirrhosis (Child-Pugh Class B or C) or a prior decompensation event
      b. compensated cirrhosis with evidence of portal hypertension (e.g. ascites, gastroesophageal varices, persistent thrombocytopenia)

c. complete biliary obstruction

2. Any indications or uses that are not FDA-approved or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Ocaliva [prescribing information]. New York, NY: Intercept Pharmaceuticals, Inc. May 2021.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
10/18/2017	Creation of Ocaliva PA Criteria
07/01/2018	Removed EHP Line of Business
01/19/2022	Updated criteria based on updated prescribing information

Review/Revision Date: 10/18/2017, 07/01/2018, 01/19/2022