UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Ocaliva

Program	Prior Authorization – Ocaliva
Medication	Ocaliva (obeticholic acid)
Issue Date	5/2016
Pharmacy and Therapeutics Approval Date	6/2017
Effective Date	8/2017

1. Background:

Ocaliva (obeticholic acid), a farnesoid X receptor (FXR) agonist, is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[1]

2. Coverage Criteria:

A. Initial Authorization

1. Ocaliva will be approved based on **all** of the following criteria:

a. Diagnosis of primary biliary cholangitis (aka primary biliary cirrhosis)

-AND-

b. **One** of the following:

(1) **Both** of the following:

(a) Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal after at least 12 consecutive months of treatment with ursodeoxycholic acid (e.g. Urso, ursodiol)
(b) Used in combination with ursodeoxycholic acid (e.g. Urso, ursodiol)

-OR-

(2) History of contraindication or intolerance to ursodeoxycholic acid (e.g. Urso, ursodiol)

-AND-

c. Prescribed by one of the following:

(1) Hepatologist
(2) Gastroenterologist

Initial authorization will be issued for 12 months

B. Reauthorization

1. Ocaliva will be approved based on **both** of the following criteria:

a. Submission of medical records (e.g., laboratory values) documenting a reduction in ALP level from pre-treatment baseline (i.e., prior to Ocaliva therapy) while on Ocaliva therapy

-AND-

b. Prescribed by one of the following:
(1) Hepatologist
(2) Gastroenterologist

Reauthorization will be issued for 12 months

3. References:

1. Ocaliva [package insert]. New York, NY: Intercept Pharmaceuticals, Inc.; May 2016.

Program	Prior Authorization – Ocaliva
Change Control	
Date	Change
5/2016	New program.
6/2016	Changed clinical criteria based on FDA approved label.
3/2017	Changed initial authorization duration to 12 months
6/2017	Updated reauthorization section with prescriber requirement and submission of medical records documenting a reduction in ALP to align with Employer and Individual's policy.