

## Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☒ **Commercial (Traditional)** ☒ **Commercial (Individual/Optimized)**

☐ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

**Ocaliva**<sup>TM</sup> (obeticholic acid)

### Member

Last Name: \_\_\_\_\_

First Name: \_\_\_\_\_

ID #: \_\_\_\_\_

DOB: \_\_\_\_\_ Gender: \_\_\_\_\_

Primary Care Physician: \_\_\_\_\_

Requesting Provider: \_\_\_\_\_

Prov. Phone: \_\_\_\_\_ Prov. Fax: \_\_\_\_\_

Provider Address: \_\_\_\_\_

Provider NPI: \_\_\_\_\_

Contact Name: \_\_\_\_\_

Provider Signature: \_\_\_\_\_

Date: \_\_\_\_\_

### Product Information

☐ New request ☐ Continuation request

Drug product: ☐ Ocaliva 5 mg tablet  
☐ Ocaliva 10 mg tablet

Start date (or date of next dose): \_\_\_\_\_

Date of last dose (if applicable): \_\_\_\_\_

Dosing frequency: \_\_\_\_\_

### Drug cost information

The wholesale acquisition cost for one tablet is \$190.00. The annual cost of treatment with this drug may be more than \$68,400.00.

### Precertification Requirements

Before this drug is covered, the patient must meet all of the following requirements:

1. Must have primary biliary cholangitis
2. Must have received 12 months of ursodiol therapy and have had an inadequate response or be intolerant to ursodiol
3. Must have one of the following:
  - a. Alkaline phosphatase level  $\geq 1.67$  times the upper limit of normal; or
  - b. Total bilirubin  $\geq 1$  times the upper limit of normal but  $< 2$  times the upper limit of normal
4. Must not have any of the following:
  - a. Clinically significant hepatic decompensation (e.g. known esophageal varices, poorly controlled or diuretic resistant ascites, history of variceal bleeds or related interventions)
  - b. Severe pruritus
  - c. Inadequate response to ursodiol due to patient adherence
  - d. Superimposed liver disease (e.g. hepatitis C, alcoholic liver disease)

**Note:** Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

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**Priority Health Precertification Documentation**

**A. What condition is this drug being requested for?**

- ☐ Primary biliary cholangitis  
☐ Other – rationale for use: \_\_\_\_\_

**B. When did patient begin ursodiol therapy?**

Date: \_\_\_\_\_

**C. Did the patient have an inadequate response to ursodiol?**

- ☐ Yes  
☐ No

**a. Was the inadequate response due to patient adherence?**

- ☐ Yes  
☐ No

**D. Does the patient have intolerance to ursodiol?**

- ☐ Yes  
☐ No

**E. Please provide one of the following (or send lab results to Priority Health):**

Total bilirubin: \_\_\_\_\_ mg/dL; Testing Reference Range: \_\_\_\_\_ Date drawn: \_\_\_\_\_

Alkaline phosphatase: \_\_\_\_\_ U/L; Testing Reference Range: \_\_\_\_\_ Date drawn: \_\_\_\_\_

**F. Does the patient have any of the following?**

- ☐ Clinically significant hepatic decompensation  
☐ Severe pruritus  
☐ Superimposed liver disease