Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Ocaliva (obeticholic acid)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***July 2016***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Ocaliva (obeticholic acid),

Ocaliva (obeticholic acid) is indicated for the treatment of biliary cirrhosis.

DEFINITIONS

Primary biliary cholangitis (PBC) –a chronic, progressive autoimmune cholestatic liver disease that is characterized by lymphocytic cholangitis and intralobular bile duct destruction leading to development of fibrosis, cirrhosis, and liver failure.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

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The drug, Ocaliva (obeticholic acid), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant specialist
- Must be age 18 years or older
- Must have a diagnosis of primary biliary cholangitis (PBC) defined by meeting at least TWO of the following criteria:
    - Elevated alkaline phosphatase (ALP) above the upper limit of normal (ULN) for at least 6 months based on the reference range provided by the laboratory. Chart documentation of the lab result is required.
    - Positive anti-mitochondrial antibody (AMA) titer defined by one of the following:
        - > 1:40 titer on immunofluorescence (e.g. 1:80)
        - M2 positive by enzyme-linked immunoabsorbant assay
    - Liver biopsy consistent with PBC
- Must have an adequate trial of at least 12 months with ursodiol at a dose of 13-15 mg/kg/day with an inadequate response defined as ALP 1.5-times the ULN or significant side effects/toxicity or must have a contraindication to ursodiol
- Must be used in combination with ursodiol unless there is a clinical contraindication or intolerance to ursodiol
- Must not have complete biliary obstruction
- For the 10 mg dose, must have a trial of the 5 mg dose for at least 3 months with an inadequate response defined as ALP 1.5-times the ULN

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

- Chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy
- Chart documentation that liver function tests are being monitored on an annual basis

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial
Quantity Level Limit	
Ocaliva	30 tablets per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Ocaliva (obeticholic acid) tablets package insert. New York, NY: Intercept Pharmaceuticals, Inc.; May 2016.
2. Clinical Pharmacology. www.clinicalpharmacology.com. Accessed June 2016

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*2/17, 02/18*