OBETICHOLIC ACID

Generic	Brand	HICL	GCN	Exception/Other
OBETICHOLIC ACID	OCALIVA	43438		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of primary biliary cholangitis as confirmed by at least **TWO** of the following criteria?
   - An alkaline phosphatase level of at least 1.5 times the upper limit of normal
   - The presence of antimitochondrial antibodies at a titer of 1:40 or higher
   - Histologic evidence of non-suppurativa destructive cholangitis and destruction of interlobular bile ducts

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is at least 18 years of age and older
   - The requested agent will be used in combination with ursodeoxycholic acid (e.g., Ursodiol, Urso 250, Urso Forte) in adults with an inadequate response to ursodeoxycholic acid at a dosage of 13-15mg/kg/day for at least 1 year, **OR** as monotherapy in adults unable to tolerate ursodeoxycholic acid
   - The patient does not have complete biliary obstruction
   - The medication is prescribed by or given in consultation with a gastroenterologist or hepatologist

   If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet per day.**
   APPROVAL TEXT: Renewal requires that the patient's alkaline phosphatase levels have decreased by at least 15% from baseline while on treatment with obeticholic acid. The following criteria must also be met:
   - The patient has not developed complete biliary obstruction

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

CONTINUED ON NEXT PAGE

Copyright © 2019 MedImpact Healthcare Systems, Inc. All rights reserved. This document is proprietary to MedImpact. MedImpact maintains the sole and exclusive ownership, right, title, and interest in and to this document.

OBETICHOLIC ACID

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT: The guideline named **OBETICHOLIC ACID (Ocaliva)** requires a diagnosis of primary biliary cholangitis, as confirmed by two of the following criteria:
- An alkaline phosphatase level of at least 1.5 times the upper limit of normal
- The presence of antimitochondrial antibodies at a titer of 1:40 or higher
- Histologic evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts

In addition, the following criteria must also be met.
- The patient is at least 18 years of age and older
- The requested agent will be used in combination with ursodeoxycholic acid (e.g., Ursodiol, Urso 250, Urso Forte) in adults with an inadequate response to ursodeoxycholic acid at a dosage of 13-15 mg/kg/day for at least 1 year, OR as monotherapy in adults unable to tolerate ursodeoxycholic acid
- The patient does not have complete biliary obstruction
- The medication is prescribed by or given in consultation with a gastroenterologist or hepatologist

RENEWAL CRITERIA

1. Does the patient have a diagnosis of primary biliary cholangitis and meets **ALL** of the following criteria?
   - The patient's alkaline phosphatase levels are less than 1.67-times the upper limit of normal **OR** have decreased by at least 15% from baseline while on treatment with obeticholic acid
   - The patient has not developed complete biliary obstruction

   If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet per day.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **OBETICHOLIC ACID (Ocaliva)** renewal requires that the patient's alkaline phosphatase levels are less than 1.67-times the upper limit of normal **OR** have decreased by at least 15% from baseline while on treatment with obeticholic acid. In addition, the following criteria must also be met.
   - The patient has not developed complete biliary obstruction

RATIONALE
Promote appropriate utilization of **OBETICHOLIC ACID** based on FDA approved indication.

CONTINUED ON NEXT PAGE

Copyright © 2019 MedImpact Healthcare Systems, Inc. All rights reserved. This document is proprietary to MedImpact. MedImpact maintains the sole and exclusive ownership, right, title, and interest in and to this document.

OBETICHOLIC ACID

RATIONALE (CONTINUED)

DOSAGE
- Starting Dosage: The recommended starting dosage of Ocaliva is 5 mg orally once daily in adults who have not achieved an adequate response to an appropriate dosage of UDCA for at least 1 year or are intolerant to UDCA.
- Dosage Titration: If adequate reduction in ALP and/or total bilirubin has not been achieved after 3 months of Ocaliva 5 mg once daily and the patient is tolerating Ocaliva, increase dosage to 10 mg once daily.
- Maximum Dosage: 10 mg once daily
- Administration Instructions: Take with or without food. For patients taking bile acid binding resins (e.g., cholestyramine, colestipol, colesevelam), take Ocaliva at least 4 hours before or 4 hours after taking a bile acid binding resin, or at as great an interval as possible.

FDA APPROVED INDICATION
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.

REFERENCES

- Ocaliva [Prescribing Information]. New York, NY: Intercept Pharmaceuticals, Inc. May 2016.
- Lindor KD, Gershwin ME, Poupon R, et al. Primary biliary cirrhosis. Hepatology. 2009;50:291-308.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/16
Created: 08/16
Client Approval: 09/16
P&T Approval: 08/16

Copyright © 2019 MedImpact Healthcare Systems, Inc. All rights reserved. This document is proprietary to MedImpact. MedImpact maintains the sole and exclusive ownership, right, title, and interest in and to this document.