STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OBETICHOLIC ACID

Generic	Brand	HICL	GCN	MEDISPAN	Exception/Other
OBETICHOLIC ACID	OCALIVA	43438		GPI-10 (5275006000)	

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 patient does not have cirrhosis OR has compensated cirrhosis with no evidence of portal hypertension
   - The medication is prescribed by or in consultation with a gastroenterologist or hepatologist
   - 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

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OBETICHOLIC ACID

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for approval:

A. You have primary biliary cholangitis (type of liver disease), as confirmed by TWO of the following criteria:
   1. An alkaline phosphatase level (indicator of possible liver/gallbladder problems) of at least 1.5 times the upper limit of normal
   2. The presence of antimitochondrial antibodies (indicator of body attacking its own cells) at a titer (concentration) of 1:40 or higher
   3. Histologic evidence of non-suppurative destructive cholangitis and destruction of interlobular bile ducts (you have lab data that shows you have certain symptoms of liver disease)
B. You are 18 years of age and older
C. You do not have cirrhosis (liver damage) OR have compensated cirrhosis (a type of liver condition) with no evidence of portal hypertension (high blood pressure in the major vein that leads to the liver)
D. The medication is prescribed by or in consultation with a gastroenterologist (digestive system doctor) or hepatologist (liver doctor)
E. You meet ONE of the following:
   1. You have had an inadequate response to ursodeoxycholic acid (such as Ursodiol, Urso 250, Urso Forte) at a dosage of 13-15 mg/kg/day for at least 1 year and the requested medication will be used in combination with ursodeoxycholic acid
   2. You are unable to tolerate ursodeoxycholic acid and the requested medication will be used as monotherapy (only drug used for treatment)
F. You do not have complete biliary obstruction (blockage of bile ducts)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OBETICHOLIC ACID

GUIDELINES FOR USE (CONTINUED)

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 or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **OBETICHOLIC ACID (Ocaliva)** requires the following rule(s) be met for renewal:
   A. You have primary biliary cholangitis (type of liver disease)
   B. Your alkaline phosphatase levels (indicator of possible liver/gallbladder problems) 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
   C. You have not developed complete biliary obstruction (blockage of bile ducts)

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Ocaliva.

REFERENCES

- Ocaliva [Prescribing Information]. New York, NY: Intercept Pharmaceuticals, Inc. May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/22
Created: 08/16
Client Approval: 11/21
P&T Approval: 10/21