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DRUG POLICY

Ocaliva (obeticholic acid)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Ocaliva policy is to encourage appropriate use according to clinical guidelines and/or clinical trials in the treatment of primary biliary cholangitis (PBC).

Ocaliva (obeticholic acid) is a farnesoid X receptor (FXR) agonist. FXR is a nuclear receptor expressed in the liver and intestine. FXR is a key regulator of bile acid, inflammatory, fibrotic, and metabolic pathways. FXR activation decreases the intracellular hepatocyte concentrations of bile acids by suppressing de novo synthesis from cholesterol as well as by increased transport of bile acids out of the hepatocytes. These mechanisms limit the overall size of the circulating bile acid pool while promoting choleresis, thus reducing hepatic exposure to bile acids.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Ocaliva 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.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- a. For initial requests: Pretreatment serum alkaline phosphatase (ALP) level

For continuation of therapy: Current serum alkaline phosphatase (ALP) and/or current total bilirubin level

Initial Criteria for Approval

A. Primary biliary cholangitis (PBC) (previously known as primary biliary cirrhosis)

Authorization of 6 months may be granted for treatment of PBC in members 18 years of age or older when all of the following criteria are met:

1. Diagnosis of PBC is confirmed by at least two of the following three criteria:
 - a. Biochemical evidence of cholestasis with elevation of alkaline phosphatase (ALP) level for at least 6 months duration
 - b. Presence of antimitochondrial antibodies (AMA) (titer \geq 1:40 by immunofluorescence or immunoenzymatic reactivity) or PBC-specific antinuclear antibodies (ANA) (eg, anti-gp210, anti-sp100)
 - c. Histologic evidence of PBC on liver biopsy (eg, non-suppurative inflammation and destruction of interlobular and septal bile ducts)
2. Member has an elevated serum ALP level prior to initiation of therapy with obeticholic acid
3. Member meets at least one of the following requirements:
 - a. Inadequate response to at least 12 months of prior therapy with ursodeoxycholic acid (UDCA)/ursodiol and the member will continue concomitant therapy with UDCA/ursodiol, OR
 - b. Intolerance to UDCA/ursodiol

Continuation of Therapy

Authorization of 12 months may be granted for members who have achieved or maintained a clinical benefit from Ocaliva therapy (i.e., at least a 15% reduction in ALP level, ALP level less than 1.67-times ULN, or total bilirubin less than or equal to ULN).

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Code(s), if applicable

REFERENCES

- Ocaliva [package insert]. New York, NY: Intercept Pharmaceuticals, Inc.; February 2018.
- Lindor KD, Gershwin E, Poupon R, et al. Primary biliary cirrhosis. *Hepatology*. 2009; 50:291-308
- European Association for the Study of the Liver. EASL Clinical Practice Guidelines: management of cholestatic liver diseases. *J Hepatol*. 2017;67:145-172.

POLICY HISTORY

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