OPTIMA HEALTH PLAN

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **(Pharmacy) 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Ocaliva® (obeticholic acid)

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code, if applicable:** _____

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ❑ Is the member currently being treated with the requested medication? ❑ Yes ❑ No

  If **YES**, when was the treatment with the requested medication started? _____

  AND

- ❑ Baseline alkaline phosphatase (ALP) level must be submitted _____
  (labs collected within the last 60 days of request must be submitted)

  AND

- ❑ Baseline total bilirubin level must be submitted _____
  (labs collected within the last 60 days of request must be submitted)

  AND

- ❑ Member must have a confirmed diagnosis of Primary Biliary Cholangitis (PBC) with documentation of at least two of the following **(labs/progress notes must be attached):**
  - ❑ Biochemical evidence of cholestasis with an alkaline phosphatase elevation of at least 1.5 times the upper limit normal
  - ❑ Antimitochondrial antibody (AMA): a titer of 1:40 or higher or a level that is above the laboratory upper limit of normal range
  - ❑ Evidence of nonsuppurative destructive cholangitis and destruction of interlobular bile ducts

  AND

- ❑ Member must be established on ursodeoxycholic acid (UDCA) for the last 8 months consecutively **(paid pharmacy claims for medication will be verified)**

  AND

- ❑ Alkaline phosphatase and total bilirubin levels are still above the upper limit of normal while established on ursodeoxycholic acid (UDCA) _____ **(labs collected within the last 30 days must be submitted)**

(Continued on next page)

AND

- ❑ Member must take ursodeoxycholic acid (UDCA) in combination with the requested medication due to ALP and total bilirubin levels remaining above the upper limit of normal after 8 months of consecutive claims for ursodeoxycholic acid

AND

- ❑ Medication will **NOT** be approved if the member has complete biliary obstruction

Reauthorization Approval: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must have monthly pharmacy paid claims for Ocaliva for the last 12 months

AND

- ❑ Alkaline phosphatase (ALP) level must have decreased by at least 15% from baseline **(labs collected within the last 30 days must be submitted)**

OR

- ❑ Alkaline phosphatase (ALP) level must have decreased to less than 1.67 times the upper limit of normal **(labs collected within the last 30 days must be submitted)**

AND

- ❑ Total bilirubin level must have decreased to less than or equal to the upper limit of normal **(labs collected within the last 30 days must be submitted)**

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

Patient Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee**: 5/17/2018
REVISED/UPDATED: ~~;6/15/2018; (Reformatted) 6/19/2019; 11/8/2021;~~ **11/22/2021**