PA Request Criteria

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This fax machine is located in a secure location as required by HIPAA regulations. Fax complete signed and dated forms to CVS/Caremark at . Please contact CVS/Caremark at 1-888-413-2723 with questions regarding the prior authorization process. When conditions are met, we will authorize the coverage of the medication.

Patient Name: _____ **Date:** 9/9/2024
Patient ID: _____ **Patient Date Of Birth:**
Patient Group No: _____ **Patient Phone:** _____ **Physician Name:**
NPI#: **Specialty:**
_____ **Physician Office Telephone:**
Physician Office Address: _____
_
Drug Name (specify drug) _____
Quantity: _____ **Frequency:** _____ **Strength:** _____
Route of Administration: _____ **Expected Length of Therapy:** _____
Diagnosis: _____ **ICD Code:** _____
Comments: _____
_____
_____

Please check the appropriate answer for each applicable question.

1. What is the diagnosis?
   - Primary biliary cholangitis (PBC) (previously known as primary biliary cirrhosis) (If checked, go to 2) ☐
   - Other, please specify. (If checked, no further questions) ☐
   _____
2. Does the patient have decompensated cirrhosis (e.g., Child-Pugh Class B or C) or a prior decompensation event? **Y** ☐ **N** ☐
3. Does the member have compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)? **Y** ☐ **N** ☐
4. Is the patient currently receiving Ocaliva? **Y** ☐ **N** ☐
5. Has the patient achieved or maintained a clinical benefit from Ocaliva therapy (at least a 15% reduction in alkaline phosphatase (ALP) level, ALP level less than 1.67 times upper limit of normal (ULN), or total bilirubin less than or equal to ULN) since starting therapy with Ocaliva? ACTION REQUIRED: If Yes, attach recent lab report with current serum alkaline phosphatase (ALP) and/or current total bilirubin level(s). **Y** ☐ **N** ☐
   ACTION REQUIRED: Submit supporting documentation
6. Has the diagnosis of PBC been 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 greater than 1:40 by immunofluorescence or immunoenzymatic reactivity) or PBC-specific antinuclear antibodies (ANA) (e.g., anti-gp210, anti-sp100), or C) Histologic evidence of PBC on liver biopsy (e.g., non-suppurative inflammation and destruction of interlobular and septal bile ducts)? **Y** ☐ **N** ☐
7. Was the patient's serum alkaline phosphatase (ALP) level elevated prior to initiating therapy with Ocaliva? ACTION REQUIRED: If Yes, attach pretreatment lab report with serum alkaline phosphatase (ALP) level. **Y** ☐ **N** ☐
   ACTION REQUIRED: Submit supporting documentation
8. Has the patient had an inadequate response to at least 12 months of prior therapy with ursodeoxycholic acid (UDCA)/ursodiol? **Y** ☐ **N** ☐
9. Will the patient continue concomitant therapy with UDCA/ursodiol? **Y** ☐ **N** ☐
10. Does the patient have an intolerance to therapy with UDCA/ursodiol? If Yes, indicate the patient's intolerance.
    - Yes (If checked, go to 11) ☐

No (If checked, no further questions) ☐

11. Is the patient 18 years of age or older? **Y** ☐ **N** ☐

I attest that the medication requested is medically necessary for this patient. I further attest that the information provided is accurate and true, and that the documentation supporting this information is available for review if requested by the claims processor, the health plan sponsor, or, if applicable a state or federal regulatory agency.

Prescriber (Or Authorized) Signature and Date