

CHECKLIST FOR PRIMARY BILIARY CHOLANGITIS (PBC)

Renewal Prior Authorization (PA) for Second-Line Treatment



Leverage this checklist to organize all materials needed to submit a renewal PA for second-line treatment. We recommend you attach any and all additional information associated with laboratory values or procedures (i.e., biopsy results) when requesting a PA.¹

Note: This checklist should help to collect information for most PAs.² It is recommended to check with each plan to ensure specific requirements are addressed.²

Patient Diagnosis With ICD-10 Code:	
Medication and Strength Requested:	
Dosing Schedule:	Quantity per Month:

ALL REQUESTS

Please list the medications the patient has previously tried and failed for the treatment of this diagnosis¹:

_____	Date range: _____
_____	Date range: _____
_____	Date range: _____

Is the patient currently treated with the requested agent? Yes No

Does the patient have any of the following contraindications?^{1,3,4} (Check all that apply)

- Decompensated cirrhosis (e.g., Child-Pugh Class B or C)
- Prior decompensation event [i.e., laboratory or clinical evidence of hepatic decompensation (e.g., ascites, jaundice, variceal bleeding, hepatic encephalopathy)]
- Compensated cirrhosis with evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia)
- Complete biliary obstruction

RENEWAL REQUESTS

Has the patient had a positive response to treatment as documented by a reduction in alkaline phosphate (ALP) compared to baseline?³ Yes No

Has the patient been previously approved for second-line therapy with this health plan in the past 2 years for the treatment of PBC? Yes No

AND has 1 of the following³:

a. The patient is currently on AND will continue treatment with ursodeoxycholic acid (UCDA) with the requested agent. Yes No

OR

b. The patient has documented intolerance, contraindication, or hypersensitivity to UCDA. Yes No

AND

Has the patient had an ALP decrease of at least 15% from baseline?³ Yes No

If no: Has the patient been previously approved with a clinical PA by another health plan in the past 2 years for the treatment of PBC? Yes No

If no previous approval: Please also complete the Initial Requests form.

AND

Is the patient's total bilirubin less than or equal to the upper limit of normal (ULN)?³ Yes No

Will the patient be using second-line therapy in combination with ursodiol? Yes No

If no: Was second-line therapy initiated as monotherapy due to a prior intolerance to ursodiol?³ Yes No

If yes: Please explain: _____

Please indicate:

Date of service (if applicable) (mm/dd/yyyy): _____

Start of treatment/Start date (mm/dd/yyyy): _____

Continuation of therapy/Date of last treatment (mm/dd/yyyy): _____

1. Formulary Navigator. https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKewjS_silhpl6AhWUhyKEHVuNBBgQFnoECA0QAQ&url=https%3A%2F%2Fm.formularynavigator.com%2FFormularyNavigator%2FDocumentManager%2FDownload%3FclientDocumentId%3DqWDR5gCN5kyyJkc4QC1LIQ&usg=AOvVaw3ogfeuF4OwJp0vn2wD01ZL. Accessed September 13, 2022.
2. ReferralMD Website. <https://getreferralmd.com/2020/06/5-reasons-why-prior-authorizations-are-challenging/>. Accessed September 13, 2022.
3. Lindor KD, et al. *Hepatology*. 2018; https://www.aasld.org/sites/default/files/2022-04/PracticeGuidelines-PBC-November2018_1.pdf. Accessed September 13, 2022.
4. Lindor KD, et al. *Hepatology*. 2022;75:1012-1013.