CHECKLIST FOR PRIMARY BILIARY CHOLANGITIS (PBC)

Initial Prior Authorization (PA) for Second-Line Treatment

Leverage this checklist to organize all materials needed to submit an Initial 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 diagnosis[1]:

_____ 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

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INITIAL REQUESTS

What is the patient's baseline (within 90 days before treatment initiation) alkaline phosphate (ALP) level? _____

Is the second-line therapy prescribed by a gastroenterologist or hepatologist? ☐ Yes ☐ No

Please select the patient's diagnosis and answer any corresponding questions:

☐ **Primary Biliary Cholangitis**

Is the patient's PBC confirmed by any of the following?[3] Check all that apply.

- ☐ History of an increased ALP [i.e., greater than the upper limit of normal (ULN) for at least 6 months]
- ☐ Presence of anti-mitochondrial antibodies (AMA)
- ☐ A negative or low AMA titer AND the presence of PBC-specific antibodies*
- ☐ Liver biopsy showing histologic evidence consistent with PBC (i.e., non-suppurative destructive cholangitis and destruction of interlobular bile ducts)
- ☐ Other (Please specify): _____

Has the patient tried treatment with ursodiol for at least 1 year of continuous treatment?[3] ☐ Yes ☐ No

If yes: Did the patient have an inadequate response to the maximally tolerated dose of ursodiol?† ☐ Yes ☐ No

If inadequate response, please define: _____

If yes: Was the ursodiol dose less than 13 mg/kg/day? ☐ Yes ☐ No

If yes: Please explain why a higher dosage was not utilized: _____

_____

Will the patient be using the second-line therapy in combination with ursodiol?[3] ☐ Yes ☐ No

If no: Has the patient experienced persistent intolerable adverse effects to ursodiol, despite dosage reduction and other management interventions, which necessitates the complete discontinuation of ursodiol treatment? ☐ Yes ☐ No

If yes: Please explain the specific adverse effect leading to the discontinuation of ursodiol: _____

_____

*Anti-GP210 and/or anti-SP100 and/or antibodies against the major M2 components (PDC-E2, 2-oxo-glutaric acid dehydrogenase complex).
†An inadequate response is defined as an elevated ALP or total bilirubin > ULN.

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%2Ffm.formularynavigator.com%2FFormularyNavigator%2FDocumentManager%2FDownload%3FclientDocumentId%3DqWDR5gCN5kyyJkc4QC1LlQ&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. *Hepatol.* 2018; https://www.aasld.org/sites/default/files/2022-04/PracticeGuidelines-PBC-November2018_1.pdf. Accessed September 13, 2022.
4. Lindor KD, et al. *Hepatol.* 2022;75:1012-1013.

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