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Initiating Second-Line Therapy: What, When, and Then What?

Announcer:
Welcome to CME on ReachMD. This episode is part of our MinuteCE curriculum.

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Dr. Hirschfield:
Hello. This is CME on ReachMD, and I'm Dr. Gideon Hirschfield. I care for over 500 patients with PBC, and today I'll discuss when to initiate second-line therapy in PBC.

What I'd like you to think about when you're treating a patient with PBC is what your goals of treatment are. I want you to prevent end-stage liver disease, manage symptoms, and I want your care to be intuitive. I want you to think about how can you get your patient to have the best liver tests? And that means normal alkaline phosphatase. And how can they have the best quality of life? And that means things like improving itch as best as possible.

To do that, we know that patients are started on UDCA, and then we have to see whether they respond. In the work that we've done to date, traditionally we've waited 12 months to see whether or not they've had insufficient response to UDCA. However, our work has shown, and our intuition tells us, that we can, in fact, identify the patients who are not responding well enough by as early as 6 months. And when you think about when to initiate second-line therapy, not only do I want you to think about pace, but I want you to think about thresholds. So I've said think normal: normal quality of life, normal blood tests. But remember, therefore, that you've got to have a threshold as to when you would normally think about starting that second-line treatment. We know that the threshold used in clinical trials, 1.67 times the upper limit of normal, is around an alk phos of 200 and that's a good number to remember. But I also want to tell you that if you're going to think normal, then think that any reduction in ALP is good for your patient. And don't only restrict patients to second-line treatments based on a cutoff of 200 if they are young, if they've got more liver fibrosis, if they are more symptomatic.

So when and who to treat? You need to treat the patients to prevent end-stage liver disease. You can start thinking about treating them with second-line treatments from as early as 6 months after UDCA. And you can use an individualized approach to the threshold that you use. But remember, in essence, if you had PBC, you'd want to have a normal alk phos and no symptoms. So therefore, whilst clinical trials have an entry point for second-line treatment of around an alk phos of 200, in fact, we know that patients derive benefit from having a lower alk phos and can have a lower threshold for starting second-line treatment.

You have a number of choices for second-line treatment, and you can understand when to use those by looking at the clinical trials, and you can understand that at the present time, the options include FXR agonists and PPAR agonists.

So my key takeaways today, therefore, are please identify patients for second-line therapy based on biochemical response to treatment. Remember that this can be done from 6 months but must be done by 12 months. Remember to think intuitively. You want your patient to have normal tests and a normal quality of life. Therefore, when you're thinking about the second-line treatments for your patients who are insufficient responders to UDCA or who, in fact, didn't tolerate UDCA at all, think about how your approved therapies work and think

about what they tackle and think about the chance that they will normalize the alk phos and improve symptoms, particularly pruritus.

Well, this has been a great, bite-sized discussion, but our time is up. So I thank you for listening.

Announcer:_
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