



Kim

Age 40

Kim was recently diagnosed with PBC and began first-line treatment. Her labs were taken at 6 months and showed elevated ALP levels. She doesn't have an immediate follow-up scheduled but may benefit from an evaluation given her high risk.

ALP¹

350 U/L (3.4 X ULN)
at diagnosis



229 U/L (2.2 X ULN)
at 6 months

Bilirubin²

0.5 mg/dL (0.4 x ULN)
at diagnosis



0.5 mg/dL (0.4 x ULN)
at 6 months

Time since diagnosis: 8 months

Risk factors^{3,4}: <45 years old

Symptoms: Fatigue, dry eye

Current treatment: UDCA 900 mg daily
(15 mg/kg/day)

Time on treatment: 8 months on UDCA

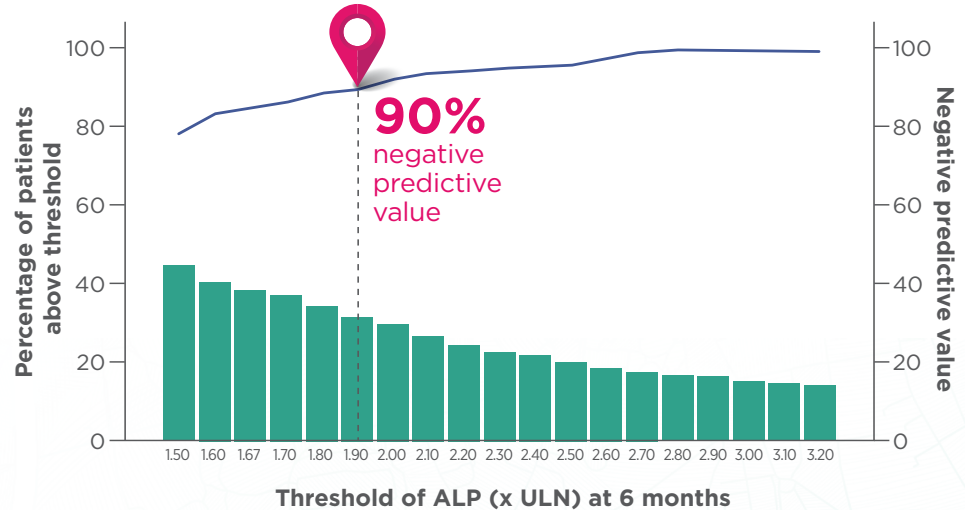


Given her lab values, should Kim have been considered for second-line treatment at her 6-month follow-up assessment?

Kim's ALP levels after 6 months on treatment are predictive of inadequate response at 12 months⁵

An analysis of the Global PBC Study database concluded that an **ALP cutoff of 1.9 x ULN at 6 months** is the suggested threshold for adding 2L therapy, with only 10% risk of overtreatment.⁵

ALP thresholds at 6 months to predict biochemical response at 1 year⁵



Dotted line shows the ALP cutoff that is associated with an NPV nearest to 90%.⁵

Adapted from Murillo Perez CF, et al; Global PBC Study Group. Optimizing therapy in primary biliary cholangitis: alkaline phosphatase at six months identifies one-year non-responders and predicts survival. *Liver Int.* 2023;43(7):1497-1506. Used under <https://creativecommons.org/licenses/by/4.0/>

Patients like Kim might benefit from reassessment of treatment as early as 6 months.

2L=second line; ALP=alkaline phosphatase; NPV=negative predictive value; PBC=primary biliary cholangitis; UDCA=ursodeoxycholic acid; ULN=upper limit of normal.

References: 1. ALKI. Mayo Clinic Laboratories. Accessed February 24, 2024. <https://www.mayocliniclabs.com/test-catalog/overview/89503#Clinical-and-Interpretive> 2. BILI3. Mayo Clinic Laboratories. Accessed February 24, 2024. <https://www.mayocliniclabs.com/test-catalog/overview/8452#Clinical-and-Interpretive> 3. Hirschfield GM, Chazouillères O, Cortez-Pinto H, et al. A consensus integrated care pathway for patients with primary biliary cholangitis: a guideline-based approach to clinical care of patients. *Expert Rev Gastroenterol Hepatol.* 2021;15(8):929-939. 4. European Association for the Study of the Liver. EASL Clinical Practice Guidelines: the diagnosis and management of patients with primary biliary cholangitis. *J Hepatol.* 2017;67(1):145-172. 5. Murillo Perez CF, Ioannou S, Hassanally I, et al; Global PBC Study Group. Optimizing therapy in primary biliary cholangitis: alkaline phosphatase at six months identifies one-year non-responders and predicts survival. *Liver Int.* 2023;43(7):1497-1506.