Expanded Approval for Daklinza/Sovaldi

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The U.S. Food and Drug Administration has expanded the approved uses of the combination hepatitis C virus (HCV) regimen of Bristol-Myers Squibb's Daklinza (daclatasvir) and Gilead Sciences' Sovaldi (sofosbuvir). Already approved to treat genotype 3 of the virus, the combo is now green-lit for those with genotype 1, as well as for individuals with advanced cirrhosis, those coinfected with HIV and people whose hep C has returned after a liver transplant.

Blaire E. Burman, MD, a liver specialist at the Virginia Mason Medical Center in Seattle, questions the impact of these new approvals. "For most patients with genotype 1," she says, "I don't see significant advantages in prescribing [Daklinza], particularly given the higher cost of its combination with Sovaldi compared with other regimens."

However, Burman adds that the Daklinza/Sovaldi combo was well studied among those with advanced liver disease, might be a favorable option for those who have had a liver transplant because it's safe to use with most immune-suppression treatments, and is possibly a good choice for those with HIV coinfection because it has shown minimal interactions with HIV treatments.

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