Hepatitis C Treatment and Risk of Hepatitis B Reactivation

February 27, 2017 By Lucinda K. Porter RN

Recently, the FDA approved a revision to the labels of certain hepatitis C medications. The label is a black box warning, designed to call attention to serious or potentially life-threatening risks. In this case, the label is on hepatitis C direct-acting antivirals (DAAs). The warning states that there is a risk of hepatitis B virus reactivation in patients coinfected with hepatitis C virus and hepatitis B virus. The labeling applies to the following hepatitis C DAAs:

- Daklinza
- Epclusa
- Harvoni
- Olysio
- Sovaldi
- Technivie
- Viekira Pak
- Zepatier

Who does this apply to: Everyone who is about to undergo hepatitis C treatment using a DAA (see above list). People with hepatitis C virus infection who are co-infected with hepatitis B virus will need to be monitored for signs of hep B reactivation. Hep B reactivation may occur during or after hep C treatment. This applies to those who are hepatitis B surface antigen (HBsAg) and hepatitis B surface antibody (HBsAb or anti-HBs) negative, but hepatitis B core antibody (HBcAb or anti-HBc) positive.

The FDA reported at least 24 cases of hepatitis B reactivation from 2013-2016. Of these, two patients died; one required a liver transplant. The FDA believes that additional cases of hepatitis B reactivation with DAA treatment for hepatitis C occurred and weren't reported.

The Bottom Line: Prior to starting hepatitis C treatment using DAAs, be sure your medical provider tests for current or prior hep B infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc).