



HEPATITIS B FOUNDATION

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CAUSE FOR A CURE

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U.S. Food and Drug Administration Advisory Panel
Rockville, MD

To Whom It May Concern,

The Hepatitis B Foundation is writing to urge the FDA Panel to approve the Hepatitis B Immune globulins (HBIG) and Nabi-HB for use in hepatitis B positive patients following liver transplantation.

For decades, liver transplantation was not a viable option for hepatitis B patients, which is the only hope and the last treatment option for those who suffer from progressive liver diseases such as cirrhosis, liver cancer and/or liver failure. The emergence of HBIG revolutionized treatment of hepatitis B patients who are now considered eligible for liver transplantation. Before HBIG, such patients were not transplanted due to the rapid recurrence of acute hepatitis B infection in the newly transplanted liver.

Introduction of treatment with HBIG (and later also with antivirals) has improved the long-term outcome of hepatitis B patients to such an extent that their prognosis is now similar to liver transplants due to other underlying pathologies.

Today, hepatitis B patients who require a transplant can expect to live a long life. Our Foundation hears regularly from these patients whose lives have been transformed by a liver transplant. Like anyone who faces death from liver failure, they are so very grateful to have drugs that extend and enhance their life expectancy.

Treatment with HBIG and antivirals, however, are required for lifelong management of hepatitis B liver transplant recipients. Premature discontinuation of HBIG, despite continuous treatment with antivirals, can result in recurrence of severe hepatitis B and, in many cases, lead to re-transplantation or even death.

HBIG and Nabi-HB have been the standard of care for hepatitis B liver transplant patients since the early 1990s. Most developed countries, except the United States, have approved HBIG for a liver transplant indication. It is inconceivable that America, with the most sophisticated health care system in the world, has still not yet officially approved HBIG for liver transplants – this despite the fact that its therapeutic value is recognized by the thought leaders and clinicians in the medical transplant field.

The lack of guidance in the HBIG label for hepatitis B transplant patients can result in inconsistent treatments, affecting long-term outcomes and creating undue financial hardship on patients whose insurance does not cover HBIG since there is no approved indication. Hence, it is paramount that label guidance be provided.

On behalf of all the hepatitis B patients whose lives have been extended and continue to be dependent upon HBIG post-liver transplantation, we ask that the FDA Panel approve HBIG and Nabi-HB for a liver transplant indication.

Sincerely,

Timothy M. Block, Ph.D.
President