

Hepatitis B Fact Sheet

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a series of fact sheets written by experts in the field of liver disease



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Hepatitis B:

When Is Treatment Needed?

Despite the availability of more drugs to treat hepatitis B, experts are still establishing when treatment should begin. Historically, researchers have used elevated alanine aminotransferase (ALT) levels as the key indicator that treatment should be started because elevated ALT levels indicate liver damage is occurring. Now, experts are not so sure.

Recent studies have found that liver damage occurs even in patients with normal ALTs (30 IU/L for men and 19 IU/L for women) and in those patients who have moderately low viral loads (HBV DNA). As a result, experts suggest that each patient should be assessed individually for ALT, viral load, hepatitis B “e” antigen status, age, gender (men are at higher risk of liver damage than women), overall health, and any family history of liver cancer.

Frequency of monitoring:

- **If patients are HBeAg positive with HBV DNA higher than 20,000 IU/mL and normal ALT levels:** Their ALT levels should be tested every three to six months, and treatment plus a liver biopsy should be considered if ALT levels increase.
- **If patients are HBeAg-negative with HBV DNA at or less than 2,000 IU/mL with normal ALTs:** Their ALT levels should be checked every three to six months and a liver biopsy and treatment should be considered if ALT levels increase.
- **If patients have undetectable HBV DNA, normal ALTs, and test positive for the hepatitis B surface antigen (HBsAg):** Their ALT levels should be checked every six to 12 months, and, if they increase, their HBV DNA levels should be checked and other potential causes of disease should be excluded.

Recommendations for Treatment

Researchers suggest the following when weighing treatment decisions:

Patient evaluation:

- In addition to a thorough physical exam and liver tests, doctors should get a family medical history with a focus on liver cancer. Any history of liver cancer supports early treatment in order to reduce its risk. Laboratory tests should include viral load (HBV DNA), liver tests, and a test for HBV genotype. A liver biopsy, which is the best way to find out if treatment is needed, is recommended for patients who have intermittent or continual elevated ALT levels or who have elevated viral load (HBV DNA) but normal ALT levels, and are older than age 35.



When Is Treatment Needed?

Whom to treat:

- **HBsAg-positive patients with HBV DNA levels higher than 20,000 IU/mL and normal ALT levels:**

- Patients should have a liver biopsy, particularly if they are older than 35. If moderate or more serious liver damage is found, treatment should be considered.
- Patients with HBV DNA levels greater than 20,000 IU/mL and elevated ALT levels (one- to two-times normal) should be treated, regardless of whether a liver biopsy is performed.

- **HBsAg-positive patients with lower viral loads:**

- Experts split on when to treat patients with normal ALT and HBV DNA levels under 20,000 IU/mL. Some experts would recommend treatment, but others would recommend waiting if patients are young and still in the immune tolerant stage of infection. However, experts agree that patients should be monitored every 3–6 months, and a liver biopsy should be considered

to determine the degree of liver damage and the need for treatment.

Role of viral load

While a viral load greater than 300 copies/mL increases the risk of liver damage, researchers continue to use 20,000 IU/mL for HBeAg-positive patients and 2,000 IU/mL for HBeAg-negative patients as the thresholds for initiating treatment. But many patients have fluctuating viral load levels, ranging from 2,000 to 20,000 IU/mL. When this occurs, experts recommend that treatment decisions be highly individualized and take into consideration the patient's age and other factors.

Which drug to use first?

Of the seven drugs available, experts recommend pegylated interferon (Pegasys) and the antivirals tenofovir (Viread) and entecavir (Baraclude) as the first-line drugs to treat HBeAg-positive or -negative patients who have never been treated. These drugs are the most potent, and the two antivirals have a low rate of causing viral resistance. Pegylated interferon does not confer drug resistance.

Nucleoside Reverse Transcriptase Inhibitors:

Tenofovir (brand name Viread) – FDA approved in 2006; *Drug resistance profile:* 0% at year 2. Combination with another HBV antiviral is recommended in patients with adefovir-resistant HBV.

Telbivudine (brand name Tyzeka) – FDA approved in 2006; *Drug resistance profile:* 25% in HBeAg positive at year 2; 11% in HBeAg negative at year 2

Entecavir (brand name Baraclude) – FDA approved in 2005; *Drug resistance profile:* 1.2% in treatment naïve at year 5; 46% in lamivudine – resistant at year 5

Adefovir (brand name Hepsera) – FDA approved in 2002; *Drug resistance profile:* 20% at year 1; 29% at year 5

Lamivudine (brand name Epivir-HBV) – FDA approved in 1998; *Drug resistance profile:* 23% at Year 5; ~70% at year 5

Interferons:

Peginterferon alfa-2a (brand name Pegasys) – FDA approved in 2005. Interferon does not cause HBV drug resistance.

Interferon alfa-2a (brand name Intron A) – FDA approved in 1991. Interferon does not cause HBV drug resistance.

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The information in this fact sheet is designed to help you understand and manage HBV and is not intended as medical advice. All persons with HBV should consult a medical practitioner for diagnosis and treatment of HBV.

For more information about hepatitis B, visit the following websites.
Hepatitis B Foundation: www.hepb.org • HIVandHepatitis.com

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