

PRESS RELEASE

People with chronic hepatitis B to benefit from guidance on new drugs and treatments

The National Institute for Health and Clinical Excellence (NICE) has today issued guidance for the NHS in England and Wales recommending the use of two new drugs for treating hepatitis B. The guidance states that :

- Peginterferon alfa-2a is recommended as an option for the initial treatment of adults with chronic hepatitis B (HBeAg-positive or HBeAg-negative), within its licensed indications.
- Adefovir dipivoxil is recommended as an option for the treatment of adults with chronic hepatitis B (HBeAg-positive or HBeAg-negative) within its licensed indications if:
 - treatment with interferon alfa or peginterferon alfa-2a has been unsuccessful, or
 - a relapse occurs after successful initial treatment, or
 - treatment with interferon alfa or peginterferon alfa-2a is poorly tolerated or contraindicated.
- Adefovir dipivoxil should not normally be given before treatment with lamivudine. It may be used either alone or in combination with lamivudine when:
 - treatment with lamivudine has resulted in viral resistance, or
 - lamivudine resistance is likely to occur rapidly (for example, in the presence of highly replicative hepatitis B disease), and development of lamivudine resistance is likely to have an adverse outcome (for example, if a flare of the infection is likely to precipitate decompensated liver disease).
- Drug treatment with peginterferon alfa-2a or adefovir dipivoxil should be initiated only by an appropriately qualified healthcare professional with expertise in the management of viral hepatitis. Continuation of therapy under shared-care arrangements with a general practitioner is appropriate.

This guidance does not apply to people with chronic hepatitis B known to be co-infected with hepatitis C, hepatitis D or HIV.

Andrew Dillon, NICE Chief Executive and Executive Lead said: "This appraisal is another example of NICE working to ensure that effective new treatments are made available to patients across the NHS. The process NICE follows is genuinely consultative and involves bringing all of the evidence together and engaging with professionals and patients. Today's guidance should lead to a faster and more uniform uptake of these important new treatments."

Professor Roger Williams, Director of the Foundation for Liver Research and Patron of the George Best Foundation says: "Today's guidance is good news as it confirms the important role these treatments play in the management of chronic hepatitis B, a condition which is estimated by the Department of Health to affect 180,000 people in the UK. The guidance will be welcomed by patients who now have the right to receive the best drugs available to treat this condition. As our own report, Hepatitis B: Out of the Shadows, published last year, shows, only a small fraction of those thought to be suffering from this condition will know that they have it. We hope that today's excellent guidance will prompt a public health campaign that will alert people to this condition and encourage them to get tested, diagnosed, treated and protected."

Professor Arie Zuckerman, Chairman of the newly launched Hepatitis B Foundation UK said: "Chronic infection with hepatitis B virus is a global problem with an estimated 350 million carriers worldwide, 20 - 25% of whom will progress over time to serious liver disease including cirrhosis and liver cancer. The number of carriers of hepatitis B among the diverse general population of the UK is not known, but an estimate of 180,000 patients with chronic hepatitis B indicates the importance of early treatment with peginterferon alpha-2a and licensed antiviral drugs of established chronic infection with hepatitis B virus. This guidance will support clinicians wishing to choose the best treatment for their patients and is to be warmly welcomed."

Ends

Notes to Editors

About NICE

1. On 1 April 2005 the National Institute for Clinical Excellence took on the functions of the Health Development Agency to form the National Institute for Health and Clinical Excellence (NICE). NICE is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
2. NICE produces guidance in three areas of health:
 - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
 - **health technologies** – guidance on the use of new and existing medicines, treatments and procedures within the NHS
 - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

About technology appraisals

3. Technology appraisals are recommendations on the use of new and existing medicines and treatments within the NHS in England and Wales, such as:
 - medicines (for example, drugs)
 - medical devices (for example, hearing aids or inhalers)
 - diagnostic techniques (tests used to identify diseases)
 - surgical procedures (for example, repairing hernias)
 - health promotion activities (for example, patient education models for diabetes).
4. Our technology appraisal recommendations are prepared by an independent Committee, who include healthcare professionals working in the NHS and people who are familiar with the issues affecting patients and carers. The Committee considers the evidence on the clinical and cost effectiveness of the technology – this includes hearing the views of, and evidence from, clinical health professionals, experts and patients.
5. NHS organisations in England and Wales have to make the resources and facilities available to enable NICE guidance to be implemented. In January 2002 the Government announced a legal obligation for the NHS to provide funding for treatments and drugs recommended by NICE as a part of its technology appraisals work programme.

About the Foundation for Liver Research

The Foundation for Liver Research was established in 1996. Its main focus of research is in autoimmune liver disease, the virological and immunological mechanisms involved in HBV and HCV chronic hepatitis, the metabolic derangements in cirrhosis, new approaches to prevention of alcohol mediated liver injury and the treatment of acute liver failure. Clinical staff of the Institute are also linked with Department of Gastroenterology of UCLH, providing both inpatient and outpatient facilities.

About the George Best Appeal

The George Best Appeal was jointly established in 2001 by the late George Best and the Foundation for Liver Research to gain a better understanding of the processes involved in liver damage from alcohol and their influence on the progression of the liver injury and in particular how self-perpetuating processes can be halted once initiated.

Information about the Foundation and the George Best Appeal can be found on this link:

<http://www.ucl.ac.uk/liver-research/>

About the Hepatitis B Foundation UK

The Foundation has been set up to help meet the challenge of hepatitis B infection by:

- offering general advice and information about hepatitis B infection and, where possible, patient-to-patient support;
- collecting up to date information about hepatitis B infection for patients, their families and health and social care professionals;
- raising awareness about the prevention of hepatitis B infection, including the key role of vaccination;
- raising awareness about the treatment and management of chronic hepatitis B infection;
- campaigning to secure the best possible services for the prevention and management of hepatitis B infection in the UK
- The Foundation's charitable status has been applied for.

<http://www.hepb.org.uk> (site under construction)