

June 2013: NICE's recommendations on adefovir dipivoxil have been updated by NICE clinical guideline 165 on hepatitis B. Please talk to your doctor for more information.

Issue date: February 2006

Adefovir dipivoxil and peginterferon alfa-2a for the treatment of chronic hepatitis B

Understanding NICE guidance –
information for people with chronic
hepatitis B, their families and carers,
and the public

Ordering information

You can download the following documents from www.nice.org.uk/TA096

- This booklet.
- The full guidance on this appraisal.
- A short version for healthcare professionals – the quick reference guide.
- The assessment report – details of all the studies that were looked at.

For printed copies of the quick reference guide or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0975 (quick reference guide)
- N0976 (information for the public).

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Contents

What is NICE guidance?	4
What is chronic hepatitis B?	4
What are adefovir dipivoxil and peginterferon alfa-2a?	5
What has NICE recommended on adefovir dipivoxil and peginterferon alfa-2a?	6
What should I do next?	7
Will NICE review its guidance?	7
Further information	back cover

What is NICE guidance?

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures within the NHS.

To produce this guidance, NICE looks at how well the medicine, equipment or procedure works and also how well it works in relation to how much it costs. This process is called an appraisal. The appraisal process involves the manufacturer of the medicine or equipment for which guidance is being produced and the organisations that represent the healthcare professionals, patients and carers who will be affected by the guidance.

NICE was asked to look at the available evidence on the use of medicines called adefovir dipivoxil and peginterferon alfa-2a to treat chronic hepatitis B. NICE was asked to provide guidance that will help the NHS in England and Wales decide when these treatments should be used.

What is chronic hepatitis B?

Hepatitis B is a disease that affects the liver. It is caused by infection with the hepatitis B virus. If the infection lasts for more than 6 months, it is called chronic hepatitis B. Many people infected with the hepatitis B virus feel well much of the time, but they can still pass the disease on to other people. And they are much more likely than someone without the disease to develop serious liver problems such as cirrhosis and cancer.

Treatments for chronic hepatitis B include medicines called interferons and lamivudine. Interferons help the body's immune system to fight the hepatitis B virus, and are given by injection, three times a week for 4 to 6 months. People don't usually take interferons for longer than this because of their side effects.

Lamivudine stops the virus from multiplying in the body. People take a tablet every day, for 12 months at first, and for longer if needed. However, after a person has taken lamivudine for a long time, it often stops working because the virus has become resistant to it.

What are adefovir dipivoxil and peginterferon alfa-2a?

NICE has looked at two medicines – adefovir dipivoxil, and peginterferon alfa-2a.

Peginterferon alfa-2a is a type of interferon to which a polyethylene glycol 'tail' has been added. This helps the drug stay in the body for longer so that injections are needed only once a week rather than three times a week. Peginterferon alfa-2a is usually taken for 48 weeks. It has similar side effects to other interferons, including flu-like symptoms at the start of treatment, depression, blood problems, high blood pressure and abnormal heart rhythms.

Adefovir dipivoxil stops the hepatitis B virus from multiplying in the body, and is taken as tablets. Its side effects include nausea, diarrhoea and stomach ache, and sometimes it causes kidney problems. Adefovir dipivoxil and lamivudine have similar effects on the hepatitis B virus, but the virus is less likely to become resistant to adefovir dipivoxil than to lamivudine.

What has NICE recommended on adefovir dipivoxil and peginterferon alfa-2a?

During the appraisal, NICE's Appraisal Committee read and heard evidence from:

- high-quality studies of adefovir dipivoxil and peginterferon alfa-2a
- doctors with specialist knowledge of chronic hepatitis B and its treatment
- individuals with specialist knowledge of the issues affecting people with chronic hepatitis B
- organisations representing the views of people who will be affected by the guidance (because they have, or care for someone with, the condition or because they work in the NHS and are involved in providing care for people with the condition)
- the manufacturers of adefovir dipivoxil and peginterferon alfa-2a.

The evidence is summarised in the full guidance and additional information about the studies can be found in the assessment report for this appraisal (see 'Further information' section for details).

NICE has made the following recommendations about the use of adefovir dipivoxil and peginterferon alfa-2a to treat chronic hepatitis B within the NHS in England and Wales.

These recommendations do not apply to people who are also infected with hepatitis C or D, or HIV.

Peginterferon alfa-2a is recommended as a possible first treatment for adults with chronic hepatitis B, as long as it is suitable for the person and the exact type of hepatitis B they have.

Adefovir dipivoxil is recommended as a possible treatment for a person with chronic hepatitis B as long as it is suitable for the person and the exact type of hepatitis B they have. And if:

- treatment with peginterferon alfa-2a or another interferon called interferon alfa has not worked for that person, or
- treatment with an interferon worked at first, but the person has had a relapse, or
- the person can't take peginterferon alfa-2a or interferon alfa, or has had serious side effects from taking these medicines.

Adefovir dipivoxil should not normally be given before the person has had lamivudine treatment. It may be given – on its own or with lamivudine – when:

- the person's hepatitis B virus has become resistant to lamivudine, or
- the virus is likely to become resistant to lamivudine quickly and the resistance could cause problems for the person, such as serious liver disease.

NICE has recommended that treatment with peginterferon alfa-2a or adefovir dipivoxil should be started only by a doctor who specialises in treating viral hepatitis. This specialist may then set up an arrangement so that the person's GP can continue prescribing the medicine, with advice and guidance from the specialist (this is called a shared-care arrangement).

What should I do next?

If you or someone you care for has chronic hepatitis B, you should discuss this guidance with your doctor.

Will NICE review its guidance?

Yes. The guidance will be considered for review in February 2007.

Further information

The NICE website (www.nice.org.uk) has further information about NICE and the full guidance on adefovir dipivoxil and peginterferon alfa-2a for the treatment of chronic hepatitis B that has been issued to the NHS. The assessment report, which contains details of the studies that were looked at, is also available from the NICE website. A short version of the guidance (a 'quick reference guide') is available on the website and from the NHS Response Line (phone 0870 1555 455 and quote reference number N0975).

You can find more information about chronic hepatitis B on the NHS Direct website (www.nhsdirect.nhs.uk). You can also phone NHS Direct on 0845 46 47.

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