

Chronic hepatitis B

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About this information

NICE clinical guidelines advise the NHS on caring for people with specific conditions or diseases and the treatments they should receive. The information applies to people using the NHS in England and Wales.

This information explains the advice about chronic hepatitis B that is set out in NICE clinical guideline 165.

All of the treatment and care that NICE recommends is in line with the NHS Constitution (<u>https://www.gov.uk/government/publications/the-nhs-constitution-for-england</u>). NICE has also produced advice on improving the experience of care for adults using the NHS. For more information see 'About care in the NHS' on our website (<u>www.nice.org.uk/nhscare</u>).

Does this information apply to me?

Yes, if you are an adult, child or young person who has been diagnosed with chronic hepatitis B, or are the parent or carer of a person with chronic hepatitis B.

It does not apply if you have had a liver transplant, have acute hepatitis B or if you have \underline{HIV} as well as hepatitis B.

Chronic hepatitis B

Chronic hepatitis B occurs in people who are infected with the hepatitis B virus (or HBV for short). The virus passes from one person to another through contact with infected blood or body fluids, most commonly through unprotected sex, sharing equipment to inject drugs, or from mother to baby during or after birth. Many people who become infected with HBV develop a short-term (acute) infection and then clear the virus naturally. Some people develop a long-term infection, which is known as chronic hepatitis B.

HBV infection is diagnosed by having a blood test. People who are infected with HBV will test positive for a protein that sits on the surface of the virus (called <u>hepatitis B surface</u> <u>antigen</u>, or HBsAg). People who remain HBsAg positive for at least 6 months are diagnosed with chronic hepatitis B.

Chronic hepatitis B affects the liver and can cause serious health problems if left untreated. These include scarring of the liver (called <u>fibrosis</u> or <u>cirrhosis</u>), liver failure (called decompensation) and liver cancer (called hepatocellular carcinoma, or HCC). Drug treatments are available that substantially reduce the risk of developing these conditions. Although treatment leads to a full recovery in some people, most people with chronic hepatitis B will need lifelong treatment.

Often people with chronic hepatitis B do not have any symptoms. This means that they may need to start treatment as their condition develops, even though they may not feel unwell. It is therefore very important that the person understands and adheres to treatment and monitoring as prescribed.

Your healthcare team

The various types of treatment described may be provided by a range of healthcare professionals who specialise in different treatments. These could include specialist doctors such as hepatologists (liver specialists), gastroenterologists (specialists in abdominal health), paediatricians (specialists in children's health) or infectious disease specialists, as well as GPs, specialist nurses and midwives.

A member of your healthcare team should discuss chronic hepatitis B with you and explain the tests and treatments for it in detail. You should have the opportunity to ask any questions you have – there is a <u>list of questions</u> you might like to ask to help you with this.

Some treatments described may not be suitable for you, depending on your exact circumstances. If you think that your treatment or care does not match this advice, talk to your healthcare team.

Being referred for specialist care

People with chronic hepatitis B are usually cared for by specialist doctors. If you are diagnosed by your GP, your GP should offer you further tests and refer you to a specialist doctor. You should be offered blood tests that will provide more information about the health of your liver, the stage of your hepatitis B disease and whether you have other infections such as HIV, hepatitis C or hepatitis D.

Your GP should also arrange for you to have an ultrasound scan to check for liver cancer. The results from all of these tests should be sent with the letter referring you to the specialist. People whose livers are showing signs of failing (called <u>decompensated liver</u> <u>disease</u>) should be referred to a specialist immediately.

Pregnant women

If you are pregnant and found out that you have chronic hepatitis B through antenatal screening, you should be referred to a specialist who should see you within 6 weeks of being diagnosed. You may need treatment later in your pregnancy to reduce the chance of your baby becoming infected with the hepatitis B virus (HBV).

Tests for liver disease

The health of your liver is an important factor when making decisions about your care and about drug treatment. You will be offered a test for liver disease when you are first referred for specialist care, and at regular intervals afterwards.

Whether or not you have liver disease, or how far it has progressed, can be checked either by a scan that measures liver stiffness (a sign of <u>fibrosis</u>, or scarring of the liver), or by a

procedure called a liver biopsy. (This scan is not currently recommended in children and young people. See Testing for liver disease in children and young people below.)

The scan is done by placing a device called a probe on your abdomen. If you have a biopsy, you will be offered a local anaesthetic to help ease any discomfort you may feel. During the biopsy, a fine needle is inserted though the abdomen to remove a small sample of the liver.

Testing for liver disease in adults

A doctor or nurse should discuss the different types of tests for liver disease with you, including how accurate they are and whether they may cause any harm.

If it is the first time you are having a test for liver disease, you should be offered a scan (called transient elastography). Depending on the results of this scan, you may be offered drug treatment, or you might be offered a liver biopsy to confirm the results. Your doctor will also consider other factors when deciding whether to offer a biopsy, such as your age, whether your liver tests are normal, and the amount of the hepatitis B virus (HBV) found in your bloodstream (called <u>viral load</u>).

If you and your doctor decide you do not need drug treatment at the moment, you should be offered an annual follow-up scan for liver disease.

Testing for liver disease in children and young people

If you are a child or young person with chronic hepatitis B, whether you will be offered a liver biopsy depends on whether your liver tests are normal (called liver function) and on the amount of HBV found in your bloodstream (called viral load).

A doctor or nurse should discuss liver biopsies with you, or with a parent or carer, if appropriate. This discussion should cover the accuracy of the procedure, and whether it may cause any harm. Young children who have a liver biopsy should be offered a general anaesthetic if this is more suitable for them than having the procedure under a local anaesthetic.

Genetic tests

Genetic tests that determine the strain of the hepatitis B virus (HBV) you are infected with (genotype tests) are available and are currently used in medical research. You should not be offered a genotype test to help choose initial drug treatment.

Drug treatment

Understanding hepatitis B and how it is treated

Chronic hepatitis B is treated with drugs called <u>antivirals</u>. Antiviral drugs work by reducing the amount of virus that is found in the body.

If you have chronic hepatitis B, you or a family member or carer, if appropriate, should be given information about the following before being assessed for drug treatment:

- how the condition might change over the longer term
- how well drug treatments might work, and their possible side effects
- the different types of drug treatment you may be offered
- the aims of drug treatment and why it may not work in some people
- how the hepatitis B virus (HBV) is passed from person to person and how it can be prevented.

You may also be advised to have an \underline{HIV} test before starting drug treatment.

You should be given a written summary describing the treatment you will receive. If you are about to start taking a drug called peginterferon alfa-2a, you or a family member or carer should be given additional information about how to inject the drug.

Contact tracing

NICE has produced guidance on ways to promote and offer testing to people at

increased risk of hepatitis B and C (<u>www.nice.org.uk/ph43</u>). Healthcare professionals may ask for your help in encouraging people you have been in contact with to be tested for HBV, such as previous sexual partners.

Drug treatment in adults

A number of factors influence whether drug treatment is recommended, such as your age, the amount of virus found in the bloodstream (called <u>viral load</u>), whether your liver tests are normal (called liver function), and the extent of any liver disease (which may be called <u>fibrosis</u>, <u>cirrhosis</u> or inflammation).

If you also have HIV, hepatitis C or hepatitis D, the information on drug treatments below may not apply to you. Information on treatments for people who have chronic hepatitis B and either hepatitis C or hepatitis D is covered in Drug treatment in adults with hepatitis C or hepatitis D below.

Which drug treatment will I be offered?

- If you are starting drug treatment for the first time and your liver continues to work adequately (called <u>compensated liver disease</u>), you should be offered a drug called peginterferon alfa-2a as a first course of treatment.
- You may need to change treatment if monitoring tests suggest this is needed. If so, your doctor will offer either tenofovir disoproxil or entecavir.
- Alternatively, if your treatment is working well, your doctor may advise you to stop drug treatment altogether.
- Once you have started antiviral treatment, you should not stop taking it without speaking to your doctor.

NICE has produced guidance on the use of drug treatments in people with chronic hepatitis B (see <u>Other NICE guidance</u> for details). You should not be offered treatment with either telbivudine or adefovir dipivoxil because more effective drugs are now available. If you are taking one of these drugs, you should discuss this with your doctor.

Drug treatment in adults with decompensated liver

disease

If your liver is showing signs of failing (called <u>decompensated liver disease</u>), you should be offered entecavir as a first course of treatment, or tenofovir disoproxil if entecavir is not suitable for you. You should not be offered treatment with peginterferon alfa-2a.

Drug treatment in women who are pregnant or breastfeeding

If you have chronic hepatitis B and are pregnant or breastfeeding, a specialist doctor or nurse should discuss whether drug treatment is needed to prevent your baby from being infected with HBV.

While you are pregnant, you should be offered blood tests to check the amount of HBV in your bloodstream (called viral load). If your viral load is high, you should be offered a drug called tenofovir disoproxil in the final 3 months of pregnancy to lower the chance of your baby becoming infected with HBV. This treatment should be continued until 4 to 12 weeks after the birth. If remaining on drug treatment may benefit your own health, your doctor will suggest you continue taking treatment long term. Women who take tenofovir disoproxil during or after pregnancy should receive regular monitoring for any sudden worsening in the signs or symptoms of chronic hepatitis B (called postnatal HBV flares).

Your baby should be offered immunisation against HBV and follow-up care in line with current guidance from NICE and the Department of Health (see <u>Antiviral treatment</u> <u>recommendations for women who are pregnant or breastfeeding</u> in the NICE guideline on Hepatitis B (chronic) for details). You should be aware that there is no risk of your baby becoming infected with HBV through breastfeeding if this guidance is followed and your baby completes the immunisation course, and that you can continue taking antiviral treatment while breastfeeding.

'Off-label' drug treatment

Drugs are approved for use (licensed) in particular conditions or for particular groups of people. At the time of publication (June 2013), some of the drugs mentioned in this guideline are being recommended for use 'off label'. This means they may not be prescribed exactly as set out in the licence. You can find more information about licensing drugs at <u>NHS Choices</u>.

If a healthcare professional offers a drug treatment 'off label', they should explain the treatment and discuss the possible benefits and harms with the patient (or their parent or carer) so that they have enough information to decide whether or not to have the treatment. This is called giving informed consent. The antiviral drugs that NICE is recommending 'off label' are described in <u>Medical terms explained</u>.

Drug treatment in adults with hepatitis C or hepatitis D

If you have another viral infection as well as chronic hepatitis B, any treatment that you take should be suitable for both conditions.

If you have hepatitis C infection and chronic hepatitis B, you should be offered treatment with a peginterferon alfa and ribavirin.

If you have hepatitis D infection (also called hepatitis delta) and chronic hepatitis B you should be offered treatment with peginterferon alfa-2a if you have significant liver disease (called fibrosis). The recommended course of treatment is 48 weeks, but your doctor may advise a longer treatment course, depending on the response.

Drug treatment in children and young people

If you are a child or young person with chronic hepatitis B, you should be offered drug treatment if you have significant liver disease (called fibrosis or cirrhosis), or if your liver tests are abnormal (called abnormal liver function). If your liver continues to work adequately (called compensated liver disease) and you have not taken drug treatment before, you may be offered peginterferon alfa-2a. This treatment is usually taken for 48 weeks. You will be monitored once treatment starts and you may be offered a different treatment if monitoring tests suggest this is needed.

Drug treatment in people receiving cancer

chemotherapy or immunosuppressive therapy

People who have previously been infected with HBV and have cleared the infection may be at risk of the infection reappearing if they take immunosuppressive therapy. This is the name for a range of treatments that are given to control the body's immune response, including chemotherapy, drugs given to people having bone marrow or organ transplants, or to people who have certain diseases of the immune system.

If you are due to begin immunosuppressive therapy and test positive for <u>hepatitis B</u> <u>surface antigen</u> (HBsAg) or antibodies to hepatitis B core antigen (anti-HBc), you should have further tests before you start treatment to determine whether HBV may reappear and whether you may need to take antiviral treatment.

Monitoring

People who do not need drug treatment

Adults with 'immune-tolerant' chronic hepatitis B

'Immune-tolerant' chronic hepatitis B is the name given to an early stage in the disease process, in which the hepatitis B virus (HBV) can be found in the bloodstream but the liver is working normally with no evidence of inflammation or damage. Adults with immune-tolerant disease should have <u>liver function tests</u> every 6 months. If the results of these tests change, testing should become more frequent (every 3 months).

Adults with 'inactive' chronic hepatitis B

'Inactive' chronic hepatitis B is a form of the disease in which there are no obvious signs or symptoms of liver disease and the amount of virus in the bloodstream (<u>viral load</u>) is low. Adults with inactive disease should have annual liver function and viral load tests.

Children and young people

Children and young people whose liver is working normally and have no sign of significant liver disease (<u>fibrosis</u>) should have liver function tests every 3 months if they test positive for <u>hepatitis B e antigen (HBeAg)</u>.

Children and young people who test negative for HBeAg should be seen annually by their hepatitis doctor so long as they have no significant symptoms. If the amount of HBV in their bloodstream (viral load) rises or liver tests become abnormal, this check-up should take place every 3 months.

People who are taking drug treatment

If you begin <u>antiviral</u> treatment you will need to see your hepatitis doctor or nurse more often than usual. After initial tests show your treatment is working and is not having any serious side effects, you will be able to visit the clinic less frequently.

If you are taking peginterferon alfa-2a you will need a check-up every week during the first month of treatment to look for side effects and to make sure you are injecting the drug correctly.

If you are taking drug treatment and your liver shows signs of failing (called <u>decompensated liver disease</u>) you will be seen weekly until your liver disease improves.

People who have stopped drug treatment

If you have undergone HBeAg <u>seroconversion</u> after taking drug treatment you should continue to be seen by your hepatitis doctor every 6 months to make sure the infection does not flare up again.

If you have undergone <u>hepatitis B surface antigen (HBsAg)</u> seroconversion you should be seen annually. Testing positive for hepatitis surface antibody (anti-HBs) on 2 consecutive tests means that you have cleared the infection and no longer need specialist care.

Tests for liver cancer

Adults with chronic hepatitis B who have significant scarring of the liver (<u>fibrosis</u> or <u>cirrhosis</u>) should have an ultrasound scan and a blood test every 6 months to check for liver cancer (hepatocellular carcinoma). If you do not have fibrosis or cirrhosis, these tests may still be recommended if other factors mean you could be at higher risk, such as your age, the amount of the hepatitis B virus (HBV) found in your bloodstream (<u>viral load</u>) and whether a family member has had liver cancer. If none of these factors apply to you, tests for liver cancer would not be needed.

Questions to ask about chronic hepatitis B

Finding out what's wrong (diagnosis)

- Can you tell me more about the tests you've offered me?
- What do these tests involve?
- Where will these tests be carried out? Will I need to have them in hospital?
- How long will I have to wait until I have these tests?
- How long will it take to get the results of these tests?

About your condition

- Can you tell me more about chronic hepatitis B?
- What steps can I take to protect my partner and family members from becoming infected?
- Would it help my condition if I made some changes to my lifestyle, such as drinking less alcohol or changing my diet?
- Are there any support organisations in my local area?
- Can you provide any information for my family or carers?

About tests for liver disease

- Can you tell me more about the test you've offered me?
- What does this test involve?
- Does this test pose any risks for me?
- How reliable is this test?
- How long will it take to get the results of this test?

• How will the results of this test affect what happens next?

Treatments

- Which treatments are available?
- Why you have decided to offer me this particular treatment?
- What are the pros and cons of this treatment?
- What will it involve?
- How will it help me? What effect will it have on my symptoms and everyday life? What sort of improvements might I expect?
- How long will it take to have an effect?
- Can you tell me about the risks associated with this treatment?
- Is there some other information (like a leaflet, DVD or a website) about the treatment that I can have?

Side effects

- What should I do if I get any side effects? (For example, should I call my GP, or go to the emergency department at a hospital?)
- Are there any long-term effects of taking this treatment?

Following up on your treatment

- Are there different treatments that I could try?
- Does the length or dose of my current treatment need to be changed?

For family members, friends or carers

• What can I do to help and support the person with chronic hepatitis B?

• Is there any additional support that I might benefit from or be entitled to?

Medical terms explained

Antiviral

An antiviral is a drug used to treat a viral condition. Antivirals used to treat chronic hepatitis B include entecavir, lamivudine, peginterferon alfa-2a and tenofovir disoproxil. NICE recommends these antivirals for off-label use in people with chronic hepatitis B in some circumstances. Please see the <u>NICE guideline</u> for details.

Cirrhosis

Cirrhosis occurs when the liver becomes scarred because of damage caused by hepatitis B, hepatitis C or alcohol use. Scarring (or fibrosis) causes bumps or nodules to form in the liver that prevent the liver working normally. Over time, cirrhosis can lead to liver cancer if left untreated.

Compensated liver disease

Compensated liver disease occurs when the liver is damaged but is still able to function normally.

Decompensated liver disease

Decompensated liver disease occurs when the liver is so severely damaged that it can no longer carry out its normal functions. In decompensated cirrhosis there are other serious complications such as bleeding.

Fibrosis

Fibrosis is a progressive form of liver disease that can be caused by hepatitis B or hepatitis C. Damage to liver cells results in scarring that prevents the liver from working normally.

Hepatitis B e antigen (HBeAg)

Hepatitis B e antigen is a protein produced by cells infected with the hepatitis B virus (HBV), although some variant forms of the virus do not produce the e antigen.

Hepatitis B surface antigen (HBsAg)

Hepatitis B surface antigen is a protein found on the surface of the hepatitis B virus (HBV).

HIV

HIV, or human immunodeficiency virus, is the virus that causes AIDS.

Liver function test

A liver function test is a blood test that measures liver injury. An abnormal result shows that the liver is not working normally.

Seroconversion

Seroconversion is when the results of a blood test change from negative to positive, or from positive to negative.

Viral load

Viral load is the amount of the hepatitis B virus (HBV) found in the bloodstream, and is measured by a blood test. Viral load tests are used to monitor people with chronic hepatitis B, to help decide when to start drug treatment, and to check whether treatment is working.

Sources of advice and support

British Liver Trust, 0800 652 7330
 www.britishlivertrust.org.uk

- Children's Liver Disease Foundation, 0121 212 3839
 <u>www.childliverdisease.org</u>
- Hepatitis B Foundation UK, 08000 46 1911
 <u>www.hepb.org.uk</u>

You can also go to NHS Choices (<u>www.nhs.uk</u>) for more information.

NICE is not responsible for the quality or accuracy of any information or advice provided by these organisations.

Other guidance

NICE guidance

- Hepatitis B and C: ways to promote and offer testing. NICE public health guidance 43 (2012). See <u>http://guidance.nice.org.uk/PH43</u>
- Patient experience in adult NHS services. NICE clinical guideline 138 (2012). See http://guidance.nice.org.uk/CG138.
- Medicines adherence. NICE clinical guideline 76 (2009). See <u>http://guidance.nice.org.uk/CG76</u>
- Reducing differences in the uptake of immunisations. NICE public health guidance 21 (2009). See <u>http://guidance.nice.org.uk/PH21</u>
- Hepatitis B tenofovir disoproxil fumarate. NICE technology appraisal guidance 173 (2009). See <u>http://guidance.nice.org.uk/TA173</u>
- Hepatitis B telbivudine. NICE technology appraisal guidance 154 (2008). See <u>http://guidance.nice.org.uk/TA154</u>
- Hepatitis B entecavir. NICE technology appraisal guidance 153 (2008). See <u>http://guidance.nice.org.uk/TA153</u>
- Hepatitis B (chronic) adefovir dipivoxil and pegylated interferon alfa-2a. NICE technology appraisal guidance 96 (2006). See <u>http://guidance.nice.org.uk/TA96</u>

Other relevant guidance

- Hepatitis B antenatal screening and newborn immunisation programme: Best practice guidance. Department of Health (2011). See <u>https://www.gov.uk/government/</u> <u>publications/hepatitis-b-antenatal-screening-and-newborn-immunisation-</u> <u>programme-best-practice-guidance</u>
- The Green Book: Chapter 18 Hepatitis B. Department of Health (2009). See: <u>https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18</u>

Accreditation

