

The use of interferon alfa, peginterferon alfa and ribavirin for the treatment of chronic hepatitis C

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

January 2004



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Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0428. A version in Welsh and English is also available, reference number N0429. Mae fersiwn yn Gymraeg ac yn Saesneg ar gael hefyd, rhif cyfeirnod N0429. The NICE technology appraisal on which this information is based on, *Interferon alfa (pegylated and non-pegylated) and ribavirin in the treatment of chronic hepatitis C*, is available from the NICE website (www.nice.org.uk/TA074guidance). A short version of the guidance (a 'quick reference guide') is also available on the website (www.nice.org.uk/TA074quickrefguide) and from the NHS Response Line, reference number N0427.

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What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is part of the NHS. It produces guidance (recommendations) on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures within the NHS in England and Wales.

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 interferon alfa, peginterferon alfa and ribavirin for the treatment of chronic hepatitis C. NICE was asked to provide guidance that will help the NHS in England and Wales decide when interferon alfa, peginterferon alfa and ribavirin should be used.

What is chronic hepatitis C?

Hepatitis is an inflammation of the liver. Hepatitis C is a form of this disease caused by a virus, known as the hepatitis C virus (HCV). Hepatitis C can be an 'acute' illness (that is, people recover after a few weeks) or a 'chronic' illness (that is, a long-term disease which may last for several years).

People can become infected with HCV if blood from another person who has the virus gets into their bloodstream. HCV can be spread by sharing needles when people inject illegal drugs. There is a small risk of infection from other procedures that use needles, for example tattooing, hair removal by electrolysis, body piercing and acupuncture. Before screening was started in the early 1990s, some people were infected after receiving blood or blood products, such as by a blood transfusion. Hepatitis C can also be transmitted through unprotected sex.

HCV is not a single type of virus but has several 'strains' known as genotypes. There are six main genotypes, which are called G1, G2, G3, G4, G5 and G6. People can be infected with more than one genotype at a time. G4, G5 and G6 are less common than the other genotypes.

At first, many people do not have symptoms after they have been infected with HCV. However, about 85 out of 100 people who have been infected go on to develop chronic hepatitis C, which can produce symptoms such as fatigue, nausea, weight loss and pain. The disease progresses slowly, generally over 20 to 50 years. Some people with chronic hepatitis C develop a condition called cirrhosis, which involves severe scarring (fibrosis) of the liver and can cause more severe symptoms. A small number of people develop cancer of the liver.

The amount of the virus in a person's bloodstream can be measured and is known as the 'viral load'. Doctors may use a test called a liver biopsy to work out how badly damaged the liver is. This involves taking a small sample of cells from the liver.

This guidance covers people who have moderate to severe chronic hepatitis C, which means tests have shown they have considerable liver scarring and/or the inflammation has caused a substantial number of liver cells to die.

What are interferon alfa, peginterferon alfa and ribavirin?

Interferon alfa is a drug which destroys the HCV virus. Peginterferon alfa is a longer-acting version of interferon alfa, meaning that people don't need to take it as often. When one of these drugs is used on its own, this is known as monotherapy. Interferon alfa or peginterferon alfa can be used together with another antiviral drug called ribavirin. Treatment like this, with more than one antiviral drug, is called combination therapy.

HCV genotypes respond differently to treatment. Studies of peginterferon + ribavirin combination therapy have shown that treatment is successful in about 75 to 85 out of 100 people infected with G2 or G3 and in about 40 to 50 out of 100 people infected by G1. For infection with G4, G5 and G6, it seems that treatment is successful in between 40 and 80 people out of 100.

What has NICE recommended on interferon alfa, peginterferon alfa and ribavirin for treating chronic hepatitis C?

During the appraisal, NICE's Appraisal Committee considered evidence from:

- good-quality studies of the three drugs
- doctors with specialist knowledge of chronic hepatitis C and its treatment
- individuals with specialist knowledge of the issues affecting people with chronic hepatitis C
- 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 the drugs.

The evidence is summarised in the full guidance (see 'Further information', page 12). More information about the studies is provided in the assessment report for this appraisal (see 'Further information', page 12).

NICE has made the following recommendations about the use of interferon alfa, peginterferon alfa and ribavirin to treat chronic hepatitis C within the NHS in England and Wales.

1. Combination therapy with peginterferon alfa + ribavirin should be used to treat people aged 18 years or older who have moderate to severe chronic hepatitis C, whether or not they have been treated before with interferon alfa or peginterferon alfa monotherapy or with interferon alfa + ribavirin combination therapy. NICE has not recommended re-treatment for people who have previously been treated with peginterferon alfa + ribavirin combination therapy.
2. The length of the treatment depends on the HCV genotype and how well a person initially responds to the drugs.
 - For people infected with HCV genotypes G2 and/or G3, treatment should last for 24 weeks.
 - For people infected with HCV genotypes G1, G4, G5 or G6, or more than one of these genotypes, treatment should first be for 12 weeks. The viral load should be measured at this time; if it has reduced to less than one hundredth of its level at the start of treatment, treatment should continue for a

further 36 weeks. If the viral load has not reduced to this level, treatment should be stopped.

3. People who are currently being treated with interferon alfa may be switched to peginterferon alfa.
4. People who cannot take ribavirin, or have bad side effects from it, should be treated with peginterferon alfa monotherapy for 12 weeks. Treatment should continue for a further 36 weeks if the viral load has reduced to less than one hundredth of its original level, or stopped after 12 weeks if it has not.
5. People who are likely to have complications from the procedure do not need to have a liver biopsy to find out how extensive their liver damage is before treatment is started. This includes people with a condition that causes excessive bleeding known as haemophilia, people who had complications from a previous liver biopsy, and people who have significant symptoms of HCV infection in parts of the body other than in the liver.
6. Because there is not enough evidence on the use of the drugs in certain groups of people, NICE has not recommended using combination therapy with either interferon alfa or peginterferon alfa for:

- people who have previously had combination therapy with peginterferon alfa, and/or
- people aged under 18, and/or
- people who have had a liver transplant.

What should I do next?

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

Will NICE review its guidance?

Yes. The guidance will be reviewed in November 2006. However, before then, the results are expected from two clinical studies of the effects of treatment with interferon alfa, peginterferon alfa and ribavirin for mild chronic hepatitis C, which was not considered in this appraisal. When the results are published, NICE will consider whether this guidance needs to be changed to take account of them.

Further information

The NICE website (www.nice.org.uk) has further information about NICE and the full guidance on interferon alfa (pegylated and non-pegylated) and ribavirin for the treatment of chronic hepatitis C 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 also available on the website and from the NHS Response Line (telephone 0870 1555 455 and quote reference number N0427).

If you have access to the Internet, you can find more information about chronic hepatitis C on the NHS Direct website (www.nhsdirect.nhs.uk). You can also phone NHS Direct on 0845 46 47.



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