National Institute for Health and Clinical Excellence

Tel: 0845 003 7782
www.nice.org.uk

Ref: 2010/133

FOR IMMEDIATE RELEASE: 22 SEPTEMBER 2010

PRESS RELEASE

200th NICE technology appraisal guidance to help tackle growing hepatitis C problem

NICE has today (22 September) published its 200th technology appraisal guidance. A partial update of the existing NICE guidance on the use of peginterferon alfa (2a or 2b) and ribavirin for the treatment of chronic hepatitis C, this new guidance reflects changes in the marketing authorisations for peginterferon alfa (2a and 2b), and recommends their wider use, and, where appropriate, shorter treatment durations, for adults with the disease.

The guidance advises that:

- Combination therapy with peginterferon alfa (2a or 2b) and ribavirin is recommended as a treatment option for adults with chronic hepatitis C who have been treated previously with peginterferon alfa (2a or 2b) and ribavirin in combination, or with peginterferon alfa monotherapy, and whose condition either did not respond to treatment, or responded initially to treatment but then relapsed, **or** for adults who are also infected with HIV

- Shortened courses of combination therapy with peginterferon alfa (2a or 2b) and ribavirin are recommended for the treatment of adults with chronic hepatitis C who have a rapid virological response to treatment at week 4 that is identified by a highly sensitive test, and who are considered suitable for a shortened course of treatment.

Sir Andrew Dillon, NICE Chief Executive, said: “From our very first recommendations, in 1999, NICE has never been far from the headlines. These technology appraisals, as challenging, contentious and emotive as they sometimes are, have helped to improve access to drugs and other treatments which have made a difference to the lives of hundreds of thousands of patients. The NHS cares for millions of patients each year with a wide range of potentially life threatening conditions – including cancer, heart disease, diabetes, respiratory disease and mental illness – and all these patients should have access to the best treatments. Because resources are limited, we carefully weigh all the available evidence to make sure that NHS money is spent on those that have the most benefit for patients. The guidance we have issued today, like the 199 that have preceded it, was developed by means of a transparent and consultative process that is held up as an example of excellence worldwide.

He continued: “A recent All Party Parliamentary Hepatology Group report on hepatitis C identified the disease as being one of the main reasons for the large rise in the number of people dying from liver disease. The report estimates that there could be as many as 466,000 people living with hepatitis C in the UK. Many people exposed to the disease have no idea they have it since it can remain symptomless for many years. However, hepatitis C is a potentially debilitating condition, and about 80% of those with the virus go on to develop chronic hepatitis, sometimes as long as 50 years after they were first infected. By widening access to these drugs, this guidance will give clinicians and people living with hepatitis C more treatment options.“

Today’s guidance means that, out of a total of 399 recommendations made about the use of treatments in 200 NICE technology appraisals, 83% have been positive.

Ends

For more information call the NICE press office on 0845 003 7782 or 07775 583 813.

About the guidance

1. The guidance is available on the NICE website at http://guidance.nice.org.uk/TA200

About hepatitis C

2. Hepatitis C is a disease of the liver caused by infection with the hepatitis C virus (HCV). Generally the virus is primarily acquired through percutaneous exposure through the skin (e.g. through injecting drug use) to contaminated blood.
3. Since the viral inactivation programme was implemented in the mid-1980s and blood donor screening started in 1991, the transmission of HCV in the UK, via transfusion of blood, blood products or organ transplantation, has all but ceased. However, injecting

drug use, and cosmetic and other practices involving percutaneous exposure remain common routes of transmission.

4. Estimates from the Health Protection Agency suggest that approximately 142,000 people between the ages of 15-59 years had chronic HCV in England and Wales in 2003; a prevalence rate of 0.44% in this age group. More than 90% of all newly diagnosed infections in the UK occur in injecting drug users.

5. People infected with HCV are often asymptomatic, but about 20% will develop acute hepatitis and will experience non-specific symptoms including malaise, weakness and anorexia. About 80% of those infected with the virus go on to develop chronic hepatitis. The rate of progression from mild to severe diease is slow but variable, taking about 20–50 years from the time of infection. About 30% of infected people develop cirrhosis within 20–30 years, and some of these people are at a high risk of developing hepatocellular carcinoma. . Some people with end-stage liver disease or hepatocellular carcinoma may require liver transplantation.

6. For the majority of people with hepatitis C (regardless of disease severity), the standard treatment is combination therapy with ribavirin and either peginterferon alfa-2a or peginterferon alfa-2b. Monotherapy with peginterferon alfa is used only for people unable to tolerate ribavirin (in line with NICE guidance TA75 and TA106).

7. **Peginterferon alfa-2a** (Pegasys, Roche Products) has a UK marketing authorisation for 'the treatment of chronic hepatitis C in adult patients who are positive for serum HCV-RNA, including patients with compensated cirrhosis and/or who are co-infected with clinically stable HIV'. The preferred treatment regimen is in combination with ribavirin, but monotherapy is indicated in cases of intolerance or contraindication to ribavirin.

8. A weekly course of treatment with peginterferon alfa-2a (180 micrograms) costs £126.91.

9. **Peginterferon alfa-2b** (ViraferonPeg, Schering-Plough (part of Merck Sharpe & Dohme)) has a UK marketing authorisation for 'the treatment of adult patients with chronic hepatitis C who are positive for HCV-RNA, including patients with compensated cirrhosis and/or co-infected with clinically stable HIV'. The preferred treatment regimen is in combination with ribavirin, but monotherapy with peginterferon alfa-2b is indicated in cases of intolerance or contraindication to ribavirin.

10. A weekly course of peginterferon alfa-2b (average of 120 micrograms) costs £162.60.

11. Two forms of **ribavirin** (Copegus, Roche Products; Rebetol, Schering-Plough (part of Merck Sharpe & Dohme)) are currently available. Each product is indicated for the treatment of chronic hepatitis C and must be used only as part of a combination regimen with peginterferon alfa or interferon alfa. Ribavirin monotherapy must not be used. Each product is licensed for use only in combination with the interferon products made by the same manufacturer.

12. The cost of treatment with peginterferon alfa-2a plus ribavirin (Copegus) is estimated to be £3215 for 16 weeks or £4824 for 24 weeks (for people with genotypes 2 or 3) and £11,425 for 48 weeks of therapy (for people with genotypes 1 or 4). For people treated with peginterferon alfa-2b plus ribavirin (Rebetol), the cost is £5540 for 24 weeks or £11,081 for 48 weeks of therapy (for people with genotype 1).

200 technology appraisals

13. NICE published its first full technology appraisal guidance – on the removal of wisdom teeth, in April 2000.

14. Since then, the Institute has published, on average, 20 technology appraisals each year, covering new drugs and treatments across all the major disease areas.

15. The Institute has produced appraisals ranging from artificial joints used in hip replacement surgery; surgical treatment for hernias; drugs for a variety of cancers; treatments for smoking cessation; drugs and surgery for obesity; drugs to treat bipolar disorder and many more.

16. There have been 399 recommendations made in the technology appraisals published to date. The majority of these recommendations have suggested full or optimised use (groups have been identified where the technologies are most effective) of technologies. Specifically 251 (65%) of the recommendations have recommended technologies for

routine use in line with their marketing authorisation and/or UK clinical practice, 70 (18%) for optimised use and 24 (6%) for use in research settings only. Only 11% of decisions by NICE did not recommend the use of a technology on the NHS. In most instances, a drug is not recommended because there is a lack of evidence for its clinical effectiveness or if the treatment is not considered to be a cost-effective use of NHS resources, compared with current NHS practice.

About NICE

17. 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.

18. 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, procedures and medical technologies within the NHS
- **clinical practice –** guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.