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Quick reference guide

Interferon alfa (pegylated and non-pegylated) and ribavirin for the treatment of chronic hepatitis C

NOTE: This is a review and extension of Technology Appraisal Guidance No. 14 issued in October 2000.

The Institute reviews each piece of guidance it issues. This review and re-appraisal has resulted in an extension to the guidance: combination therapy with pegylated interferon alfa and ribavirin is recommended for the treatment of people aged 18 years and over with moderate to severe chronic hepatitis C.

1 Guidance

- 1.1 Combination therapy with peginterferon alfa and ribavirin is recommended within its licensed indications for the treatment of people aged 18 years and over with moderate to severe chronic hepatitis C (CHC), defined as histological evidence of significant scarring (fibrosis) and/or significant necrotic inflammation.
- 1.2 People with moderate to severe CHC are suitable for treatment if they have:
- not previously been treated with interferon alfa or peginterferon alfa, or
 - been treated previously with interferon alfa (as monotherapy or in combination therapy), and/or
 - previously received peginterferon alfa monotherapy only and responded at the end of treatment but subsequently relapsed, or did not respond at the end of treatment.
- 1.3 People currently being treated with interferon alfa, either as combination therapy or monotherapy, may be switched to the corresponding therapy with peginterferon alfa.
- 1.4 Treatment for the groups identified in Sections 1.1 and 1.2 should be as follows.
- People infected with hepatitis C virus (HCV) of genotype 2 and/or 3 should be treated for 24 weeks.
 - For people infected with HCV of genotype 1, 4, 5 or 6, initial treatment should be for 12 weeks. Only people showing, at 12 weeks, a reduction in viral load to less than 1% of its level at the start of treatment (at least a 2-log reduction, see the full guidance) should continue treatment until 48 weeks. For people in whom viral load at 12 weeks exceeds 1% of its level at the start of treatment, treatment should be discontinued.
- People infected with more than one genotype that includes one or more of genotypes 1, 4, 5, or 6 should be treated as for genotype 1.
- 1.5 People satisfying the conditions in sections 1.1 and 1.2 but for whom ribavirin is contraindicated or is not tolerated should be treated with peginterferon alfa monotherapy. Regardless of genotype, individuals should be tested for viral load at 12 weeks, and if the viral load has reduced to less than 1% of its level at the start of treatment, treatment should be continued for a total of 48 weeks. If viral load has not fallen to this extent, treatment should stop at 12 weeks.
- 1.6 People for whom liver biopsy poses a substantial risk (such as those with haemophilia, or those who have experienced an adverse event after undergoing a previous liver biopsy), and people with symptoms of extra-hepatic HCV infection sufficient to impair quality of life, may be treated on clinical grounds without prior histological classification.
- 1.7 There is insufficient evidence to recommend combination therapy using peginterferon alfa or interferon alfa in people who:
- have previously been treated with combination therapy using peginterferon alfa, and/or

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This guidance is written in the following context:

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

- are younger than 18 years of age, and/or
- have had a liver transplantation. Treatment of CHC recurrence after liver transplantation (whether or not the person had been treated with interferon alfa or peginterferon alfa therapy at any time before transplantation) should be considered as experimental and carried out only in the context of a clinical trial.

2 Implementation

2.1 Implications for the NHS

- 2.1.1 The total increased drug cost to the NHS in England and Wales over the next 2 years is estimated to be about £10.5 million per year, based on the following assumptions: (1) all people currently receiving treatment with peginterferon alfa or interferon alfa go on to receive combination therapy with peginterferon alfa and ribavirin; (2) people who have not responded to previous treatment are re-treated (see 1.2) and this re-treatment occurs over the next 2 years; (3) people infected with HCV genotype 1 are tested after 12 weeks of combination therapy and treatment is stopped if the response to treatment is inadequate (see 1.4).

No account has been taken of possible increases in treatment costs because of an increase in the

number of people able to benefit from treatment as a consequence of this guidance or because of increased awareness of the disease and improved treatments. Further details of the cost estimation are included in the full guidance (see Further information).

2.2 Local implementation and audit

- 2.2.1 Treatment for CHC should be provided by physicians who are expert and experienced in the diagnosis and management of viral hepatitis, and a clinical nurse specialist for hepatitis with access to supportive services including an accredited virology laboratory, a liver pathologist and a radiology department, consistent with Department of Health (2002) Hepatitis C Strategy for England. London: Department of Health.
- 2.2.2 All clinicians who care for people with CHC should review their current practice and policies to take account of the guidance. Local guidelines, protocols or care pathways that refer to the care of people with CHC should incorporate the guidance.
- 2.2.3 Suggestions for audit to measure compliance locally with the guidance are included in the full guidance.

Further information

Distribution

The distribution list for this quick reference guide is available on the NICE website at www.nice.org.uk/TA075distributionlist

Full guidance

The full guidance is available from www.nice.org.uk/TA075guidance

It contains the following sections: 1 Guidance; 2 Clinical need and practice; 3 The technology; 4 Evidence and interpretation; 5 Recommendations for further research; 6 Implications for the NHS;

7 Implementation and audit; 8 Related guidance; 9 Review of guidance.

The full guidance also gives details of the Appraisal Committee, the sources of evidence considered and suggested criteria for audit.

Information for the Public

NICE has produced information describing this guidance for people with chronic hepatitis C, their families, and the public. It is available from the NHS Response Line (see below) and from the NICE website at www.nice.org.uk/TA075publicinfoenglish (English version) and www.nice.org.uk/TA075publicinfowelsh (English and Welsh version).

Ordering information

Copies of this quick reference guide can be obtained from the NICE website at www.nice.org.uk/TA075quickrefguide or from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0427. *Information for the Public* can be obtained by quoting reference number N0428 for the English version and N0429 for a version in English and Welsh.

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