EXECUTIVE SUMMARY

Chronic hepatitis C (CHC) is a chronic viral infection of the liver that may lead, through necroinflammatory activity, to progressive fibrosis, cirrhosis and liver cancer in at least 20% of patients.

Between 200,000-400,000 people in the UK are estimated to be chronically infected with the hepatitis C virus, but only 38,000 diagnosed cases have been reported. Despite earlier guidance issued by NICE and initiatives undertaken by the NHS, only a fraction of HCV-infected people are diagnosed and treated in England and Wales in comparison with other European countries.

Histologically mild CHC describes minimal/mild liver histological lesions on biopsy, independent of the alanine aminotransferase (ALT) profile. Using the Metavir scale to assess liver biopsies, approximately 32.5% of individuals with CHC would be classed as F1 (minimal portal fibrosis) and 6.4% would be classed as F0 (no fibrosis). All individuals with mild disease, defined as F1, especially those who have abnormal liver enzymes, will eventually progress to more severe disease states. A minority of patients with CHC and no necroinflammatory activity on histology, especially those without raised liver enzymes, will not typically progress to more severe fibrosis.

The standard treatment for CHC is pegylated interferon and ribavirin. The goal of treatment of CHC is viral clearance measured by a sustained virological response (SVR). This was the subject of guidance by the National Institute for Health and Clinical Excellence in 2004. England and Wales has lower rates of diagnosis and treatment of CHC than other countries in Europe and the US.

Patients with mild disease have previously been excluded from many major CHC treatment guidelines. Evidence now exists to demonstrate that treatment with pegylated interferon is safe and effective in these patients, probably delivering better results with regard to SVR than in patients with moderate/severe disease.

Clinical effectiveness of ViraferonPeg plus ribavirin

Data obtained from clinical studies demonstrate that subjects with histologically mild disease respond at least as well as individuals with moderate/severe disease when treated with a weight-based dosed (WBD) regimen of ViraferonPeg and ribavirin. In the absence of treatment, these patients would be likely to progress to more serious disease.

The beneficial effects of WBD were particularly notable in two subgroups of patients: genotype 2/3 (G2/3) infected patients and genotype 1 (G1) HCV infected patients with low viral load (LVL) at baseline (defined as <2 million copies/ml). Based on viral response at 4 weeks, shorter durations of therapy for subgroups within G2/3 and G1 LVL may be recommended.

Cost-effectiveness of ViraferonPeg and ribavirin

ViraferonPeg plus ribavirin is highly cost-effective relative to both no treatment and non-pegylated interferon alfa-2b plus ribavirin in the treatment of mild (F1) CHC, costing £1,193 per quality adjusted life-year (QALY) gained relative to no treatment and £1,739 per QALY relative to non-pegylated interferon alfa-2b plus ribavirin. This finding was extremely robust, with no sensitivity analysis increasing any cost effectiveness ratio above £8,789 per QALY gained.

Budgetary implications and NHS impact

Extending the current NICE guidance to include patients with fibrosis severity F1 and elevated ALT would mean that an additional 6,600 patients would be treated over the next five years at a total cost of £52 million. Once the backlog of prevalent patients has been treated, treating incident patients only would cost in the region of £5-6 million per year.