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BY E-MAIL

Dear Alana,

HEALTH TECHNOLOGY APPRAISAL – Interferon alfa and ribavirin for the treatment of mild chronic hepatitis C – part review of existing guidance number 75

Thank you for the opportunity to comment on the Assessment Report produced by the Southampton Health Technology Assessment Centre (SHTAC) for the above technology appraisal.

Overall, we believe that the report provides a fair review of the available clinical and cost effectiveness evidence base. However, we would like to draw the following points to the attention of the Appraisal Committee.

Clinical Effectiveness

1. Liver Biopsy

The HTA report states: "There is less of a necessity to gauge disease severity to decide if treatment is necessary" (p.134). Since the report concludes that it is both clinically and cost effective to treat mild CHC patients irrespective of genotype, the use of liver biopsy results to decide whether to treat patients with pegylated interferons appears to become irrelevant for the treatment decision.

Consequently, treatment guidelines with respect to this point are likely to need to be revised.

2. Evidence base for mild CHC treatment decision

Roche strongly supports the comments of the HTA group that "The emphasis is now on when to treat rather than whether to treat" (p.134). This summary is reflective of the available evidence base presented within the report.

The significance of the statement that "the evidence from this report suggests that patients with histologically mild HCV (all genotypes) can be treated with anti-viral therapy" should not be underestimated, especially when considering current treatment practice in the UK.

Consequently, Roche strongly supports the HTA recommendation to update UK guidelines on the treatment of CHC in the light of these HTA Assessment Report findings (p.135). The conclusion of the report that the early treatment of mild CHC (for all genotypes 1, 2, 3 and 4) is a more clinically effective **and** cost effective strategy compared to waiting and treating only when a CHC patient is moderate/severe, will significantly challenge current UK clinical practice.

Cost Effectiveness

1. Early Stopping evidence base for Pegylated interferon alfa-2b

Considering existing NICE guidance and current clinical practice within the moderate/severe population, the cost effectiveness results within the HTA report that include a 24 week genotype 2/3 treatment duration and the early stopping of genotype 1 patients are the most clinically relevant ICERs upon which to formulate NICE guidance (p.121). The ICERs for pegylated interferon alfa-2b relating to this most clinically relevant scenario as reported in tables 48 to 50 (p.121) should be treated with caution by the Appraisal Committee since these ICERs are not based upon data from a Mild CHC population. Furthermore, the possible effect that early stopping of pegylated alfa-2b has upon subsequent SVRs is unknown, as no specific data is available for pegylated interferon alfa-2b in this area.

We hope that these comments are helpful for the Appraisal Committee

Please do not hesitate to contact me if you require any further clarification or explanation of our feedback.

Yours sincerely.