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Merck Serono UK


Peter House
Oxford Street
Manchester
M1 5AN

Tel: 0161 209 3855

Fax: 0161 209 3889

Email: nice@nice.org.uk

www.nice.org.uk

Via Email

Dear 

**Single Technology Appraisal
Cetuximab for Locally Advanced Squamous Cell Cancer
of the Head and Neck**

With reference to the decision of the Appeal Panel on the appraisal of cetuximab for the treatment of patients with locally advanced squamous cell cancer of the head and neck (sent to you on 2 October 2007) the Institute is seeking further evidence to inform future deliberations of the Appraisal Committee.

Specifically, the Appeal Panel instructs the Appraisal Committee to 'reassess the evidence for the clinical and cost-effectiveness of cetuximab in combination in patients who meet (in whole or in part) the criteria defined by Merck Serono'.

Following the Appeal Panel's instruction I am writing to request that Merck-Serono make available the following:

- Median survival data (include their 95% confidence intervals) derived from the Bonner study, for each of the following Karnofsky performance scores – 100, 90, 80, 70 and less.
- Any other data in its possession that would enable the Appraisal Committee to assess the clinical and cost effectiveness of cetuximab according to the decision problem defined by Merck Serono.

To allow for consideration of both clinical and cost effectiveness of cetuximab in patients with varying Karnofsky performance scores, Merck Serono is

asked to also provide incremental cost-effectiveness ratios for each of these patient groups listed in the first bullet point above.

To assist the Appraisal Committee in its reconsideration of the evidence for the use of carboplatin as a treatment option for patients in whom cisplatin-based chemoradiotherapy is considered an inappropriate option, the Institute is inviting Merck Serono to submit further evidence on the efficacy of carboplatin alone and on the safety or toxicity of carboplatin plus fluorouracil in patients with locally advanced squamous cell cancer of the head and neck.

Your submission is gladly received at the earliest available opportunity but no later than **Monday 12 November 2007 at 5pm**.

Please submit your response via email to Christopher Feinmann, Project Manager on christopher.feinmann@nice.org.uk. If you have any technical queries, please contact Ms Nicola Hay, Technical Analyst, on nicola.hay@nice.org.uk.

Yours sincerely

Meindert Boysen
Associate Director Single Technology Appraisals
Centre for Health Technology Evaluation