

csas

Commissioning Support
Appraisals Service

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National Institute for Health and Clinical Excellence
Level 1A, City Tower
Piccadilly Plaza
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10th December 2010

Dear Ms Moore

Regarding: Erlotinib monotherapy for the maintenance treatment of non-small-cell lung cancer

On behalf of Commissioning Support, Appraisals Service (CSAS), Solutions for Public Health, I would like to submit our comments on the appraisal consultation document for Erlotinib monotherapy for the maintenance treatment of non-small-cell lung cancer. We are in agreement with the recommendations in the ACD not to recommend erlotinib for this indication as on the basis of the evidence considered it is unlikely that this treatment can be considered clinically and cost effective in real life clinical practice.

- The key trial presented by the manufacturer (SATURN trial) may not be representative of the UK population. The population in this trial was not typical of UK clinical practice. It had a higher proportion of South East Asians, a slightly younger, probably slightly fitter patient population, a higher proportion of never smokers and a small proportion with a positive EGFR status than would be seen in UK clinical practice. All of these factors would be associated with better outcomes. In addition, EGFR positive patients in the UK would not be treated with erlotinib.
- The SATURN trial required very frequent scans that would be unlikely to be replicated in routine clinical care.
- No patients in the SATURN trial received the most common and more effective first line treatment in the UK (pemetrexed and cisplatin for patients with non-squamous disease).
- Evaluation of patients with small cell and non small cell disease was based on post hoc stratification in this trial. CSAS agrees with the ERGs comment that this trial was not designed for these analysis and the results of this analysis should be interpreted with caution.
- CSAS supports the view of the Appraisal Committee that the true Incremental Cost-Effectiveness Ratio (ICER) was greater than those estimated by the manufacturers and the Evidence Review Group (ERG), and well above £50,000 per QALY even after considering the patient access scheme. The true benefit is also likely to be even lower than that estimated by the ERG.
- Cost effectiveness was not demonstrated for erlotinib compared with pemetrexed in patients with stable, non-squamous disease.

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- End of life criteria did not apply as the potential population eligible to receive erlotinib is large and there was no robust evidence of an extension of life of three months.

If you require any further information please do not hesitate to contact me: email

[REDACTED]

Yours sincerely