

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Cetuximab for metastatic and/or recurrent squamous cell carcinoma of the head and neck (SCCHN)

Final scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of cetuximab within its licensed indication in combination with platinum-based chemotherapy for metastatic and/or recurrent squamous cell carcinoma of the head and neck.

Background

Head and neck cancer is the name given to a variety of malignant tumours that occur in the head and neck region. The most common type of malignant tumour in the head and neck region is squamous cell carcinoma. This is a heterogeneous group of tumours and can be divided into the following sites: skin and lip, oral cavity, oropharynx, larynx, hypopharynx, nasopharynx, salivary glands, nasal cavity and paranasal sinuses, and external auditory meatus and middle ear.

Squamous cell carcinoma of the head and neck (SCCHN) is three to four times more common in men than in women, and most tend to occur from age 40 onwards. Some of the rarer tumours such as nasopharyngeal carcinomas and salivary gland tumours occur in people under the age of 40 years. The development of head and neck cancer is associated with tobacco, alcohol and other environmental and dietary factors.

There were approximately 8,000 new registrations for head and neck cancer in England and Wales in 2003, and 2,667 deaths in 2004. Less than 5% of people with head and neck cancer have metastatic disease at diagnosis. Approximately 20% of people with recurrent head and neck cancer have metastatic disease. The five-year survival rate is approximately 33% - this is variable depending on type of cancer, extent of disease, sex of patient, and geographical location.

Approximately 90% or all malignant tumours of the head and neck are squamous cell carcinomas of variable differentiation. The prognosis depends on the stage of the disease, which is usually categorised using the TNM classification system.

The cancer service guidelines issued by NICE in 2004 state that treatment for recurrent disease may involve surgery and/or radiotherapy and palliative care. Chemotherapy or chemoradiation is increasingly used, but reliable evidence of effectiveness is lacking and there is uncertainty about the overall impact on quality of life. The Scottish Intercollegiate Guideline Network (SIGN) recommends that patients with adequate performance status should be

considered for platinum-based chemotherapy as palliative chemotherapy in patients with recurrent and/or metastatic head and neck cancer.¹

The technology

Cetuximab (Erbix, Merck-Serono Pharmaceuticals) is a recombinant monoclonal antibody that blocks the human epidermal growth factor receptor (EGFR) and thus inhibits the proliferation of cells dependent on EGFR activation for growth.

Cetuximab does not currently have a UK marketing authorisation for the treatment of metastatic and/or recurrent SCCHN. EXTREME, a randomised clinical trial examining the effect of first-line combination of cetuximab plus cisplatin or carboplatin and 5-fluorouracil compared to cisplatin or carboplatin and 5-fluorouracil in patients with recurrent of metastatic SCCHN has now completed.

Cetuximab in combination with radiation therapy is currently indicated for the treatment of patients with locally advanced SSCHN. NICE Technology Appraisal No. 145 recommends cetuximab in combination with radiotherapy as a treatment option only for patients with locally advanced squamous cell cancer of the head and neck whose Karnofsky performance-status score is 90% or greater and for whom all forms of platinum-based chemoradiotherapy treatment are contraindicated.

Intervention(s)	Cetuximab plus platinum-based chemotherapy
Population(s)	Adults with metastatic and/or recurrent squamous cell carcinoma of the head and neck for whom platinum-based chemotherapy is appropriate.
Standard comparators	Platinum-based chemotherapy regimens.
Outcomes	The outcome measures to be considered include: <ul style="list-style-type: none"> • overall survival • progression free survival • tumour response • adverse effects of treatment • health-related quality of life.

¹ SIGN Guideline No 90. Diagnosis and management of head and neck cancer. October 2006. Available from URL <http://www.sign.ac.uk/guidelines/fulltext/90/index.html>
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<p>Economic analysis</p>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The economic analysis should be based on a lifetime time horizon.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
<p>Other considerations</p>	<p>If the evidence allows, the appraisal should consider subgroups (e.g. by performance status or biomarkers), for whom the technology may be particularly effective.</p> <p>Guidance will only be issued in accordance with the marketing authorisation.</p>
<p>Related NICE recommendations</p>	<p>Related Technology Appraisals:</p> <p>Technology Appraisal No.145, June 2008. Cetuximab for the treatment of locally advanced squamous cell cancer of the head and neck.</p> <p>Ongoing appraisals. Technology Appraisal in preparation: Intensity modulated radiotherapy for head and neck cancer. Earliest anticipated date of publication: to be confirmed.</p> <p>Related Guidelines:</p> <p>Cancer Service Guidance: Improving Outcomes in Head and Neck Cancers, November 2004.</p>