NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal

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

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of erlotinib monotherapy within its licensed indication, for the maintenance treatment of non-small cell lung cancer after previous platinum containing chemotherapy

Background

Lung cancer is the third most common cause of death in the UK and the most common cause of cancer death. In England and Wales there were 33,450 new cases diagnosed in 2006, with 29,574 deaths registered in 2007. In England and Wales lung cancer has a one-year survival rate of 25% and a five-year survival rate of 7%. Non-small cell lung cancer (NSCLC) accounts for approximately 80% of all lung cancers.

Staging describes how far the cancer has spread. In stage IIIB, the tumour may be any size and has spread to lymph nodes above the collar bone or in the opposite side of the chest from the tumour; and/or to any of the organs in the thoracic cavity. Stage IV non-small cell lung cancer may have spread to lymph nodes and has spread to another lobe of the lungs or to other parts of the body, such as the brain, liver, adrenal glands, kidneys, or bone. Approximately 75% of newly diagnosed patients already have advanced (stage III or IV) disease (equating to around 24,536 patients in England and Wales), with a five-year survival rate of less than 1%.

Approximately 25% of patients with advanced NSCLC receive first-line chemotherapy and around 30-40% of these patients may receive second-line therapy. Treatment options for stage IIIB or IV NSCLC include radiation therapy, chemotherapy with radiotherapy, and chemotherapy alone. Chemotherapy may be recommended for patients with non-resectable stage III or IV disease if they are able to tolerate it. A NICE Clinical Guideline on lung cancer (CG24) recommends that first-line chemotherapy should include a combination of a platinum drug (cisplatin or carboplatin) and a single third generation drug, such as docetaxel, gemcitabine, paclitaxel or vinorelbine. Pemetrexed in combination with cisplatin is recommended for the first-line treatment of locally advanced or metastatic NSCLC if the histology of the tumour has been confirmed as adenocarcinoma or large-cell carcinoma (TA181). Maintenance therapy (therapy taken immediately after first line platinum containing chemotherapy, at regular intervals until disease progression) is not currently part of routine care for patients with NSCLC.

The technology

Erlotinib (Tarceva, Roche) is an orally-active epidermal growth factor receptor tyrosine kinase inhibitor. It has marketing authorisation for the treatment of patients with locally advanced or metastatic NSCLC after the failure of at least one platinum containing chemotherapy regimen.

Erlotinib does not currently have a marketing authorisation for the maintenance treatment of NSCLC. It is being studied in people with advanced NSCLC whose disease had not progressed following first line platinum-based chemotherapy. Erlotinib is licensed for treatment of locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.

Intervention(s)	Erlotinib monotherapy
Population(s)	People with advanced or metastatic (stage IIIB and IV) NSCLC whose disease has not progressed following treatment with platinum-based first-line chemotherapy
Comparators	• Best supportive care, which may include palliative radiotherapy care, corticosteroids (without maintenance therapy) and watchful waiting alone Additionally, people with non-squamous NSCLC: • Pemetrexed monotherapy[1]
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rates • adverse effects of treatment • health-related quality of life
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal

[1] Dependent on the outcome of the ongoing STA: pemetrexed for maintenance treatment of non-small cell lunch cancer, pemetrexed may be included as a comparator.

	Social Services perspective.
Other considerations	If the evidence allows, subgroups will be considered. These may include subgroups defined by: performance status, histology (squamous/ non squamous), smoking status, EGFR mutational status, and response to first line treatment Guidance will only be issued in accordance with the marketing authorisation.
Related NICE recommendations	Related Technology Appraisals: Technology Appraisal No.124. August 2007, 'Pemetrexed for the treatment of non small cell lung cancer'. Technology Appraisal No.148. June 2008, 'Bevacizumab for the treatment of non-small cell lung cancer'. Technology Appraisal No. 175. July 2009, 'Gefitinib for the second-line treatment of non-small cell lung cancer'. Technology Appraisal No. 162. November 2008, 'Erlotinib for the treatment of non-small cell lung cancer'. Technology Appraisal No. 181. September 2009. 'Pemetrexed for the first-line treatment of advanced or metastatic non-small cell lung cancer'. Technology Appraisal in progress, 'Gefitinib for the first-line treatment of non-small cell lung cancer', expected date of publication June 2010. Technology Appraisal in preparation 'Erlotinib (in combination with bevacizumab) for the maintenance treatment of advanced or metastatic non-small-cell lung cancer', expected date of publication June 2011. Technology Appraisal in preparation 'Pemetrexed for maintenance treatment following first line chemotherapy for non-small-cell lung cancer', expected date of publication May 2010. Related Guidelines: Clinical Guideline No.24. February 1995, The diagnosis and treatment of lung cancer (currently being reviewed).