NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

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

Draft 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 32,715 new cases diagnosed in 2004, with 28,632 deaths registered in 2005 (around 54 deaths per 100,000 of population). 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 provided they are sufficiently fit. 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. 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 use in the first line treatment of NSCLC. It is currently being studied in trials as maintenance treatment after 4 cycles of first line chemotherapy.

Intervention(s)	Erlotinib monotherapy
Population(s)	People with advanced or metastatic NSCLC whose disease has not progressed following treatment with first line chemotherapy
Comparators	• Pemetrexed monotherapy • Best supportive care
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 Social Services perspective.
Other considerations	If the evidence allows, the following subgroups of should be considered: • subgroups defined by performance status • subgroups defined by histology (squamous/ non squamous) • subgroups defined by smoking status and

	smoking history 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. 162. November 2008, 'Erlotinib for the treatment of non-small cell lung cancer'. Technology Appraisal in progress, 'Gefitinib for the treatment of non-small cell lung cancer', expected date of publication June 2010. Technology Appraisal in progress 'Cetuximab for the treatment of advanced non-small cell lung cancer', expected date of publication TBC. Technology Appraisal in progress 'Pemetrexed for the first-line treatment of advanced or metastatic non-small cell lung cancer', expected date of publication September 2009. 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).

This topic has been formally referred as a Single Technology Appraisal (STA). NICE welcomes comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at

http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp