

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Pemetrexed for the maintenance treatment of non-small cell lung cancer

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of pemetrexed, within its licensed indications, for maintenance treatment immediately after first-line chemotherapy for non-small cell lung cancer.

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 a cancer has spread. In stage IIIB NSCLC, 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 NSCLC 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 20-40% 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. NICE Clinical Guideline 24 (Lung cancer) 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 chemotherapy until disease progression) is not currently part of routine care for patients with NSCLC.

The technology

Pemetrexed (Alimta, Eli Lilly) is an antifolate agent that works by disrupting folate-dependent metabolic processes essential for cancer cell replication and survival. It is administered as an intravenous infusion.

The CHMP has issued a positive opinion for pemetrexed for the monotherapy maintenance treatment of locally advanced or metastatic non-small cell lung cancer in patients whose disease has not progressed immediately following platinum-based chemotherapy.

Intervention(s)	Pemetrexed (maintenance treatment)
Population(s)	People with advanced or metastatic (stage IIIB and IV) NSCLC, other than those with predominately squamous histology, whose disease has not progressed following treatment with platinum-based, first-line chemotherapy
Comparators	Best supportive care, which may include palliative radiotherapy and corticosteroids (without maintenance therapy)
Outcomes	The outcome measures to be considered include: <ul style="list-style-type: none"> • health-related quality of life • overall survival • progression free survival • response rates • adverse effects of treatment
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.

<p>Other considerations</p>	<p>Guidance will only be issued in accordance with the marketing authorisation.</p> <p>If evidence allowance, the appraisal will consider sub-groups based on histology type.</p> <p>If appropriate, consideration will be given to criteria for the continuation of treatment.</p>
<p>Related NICE recommendations</p>	<p>Related Technology Appraisals:</p> <p>Technology Appraisal No.124. August 2007, 'Pemetrexed for the treatment of non small cell lung cancer'.</p> <p>Technology Appraisal in preparation 'Pemetrexed for the first-line treatment of locally advanced or metastatic non-small cell lung cancer', expected date of publication September 2009.</p> <p>Technology Appraisal in preparation 'Erlotinib in combination with bevacizumab for the maintenance treatment of non-squamous advanced or metastatic non-small-cell lung cancer after previous platinum-containing chemotherapy', date of publication TBC.</p> <p>Technology Appraisal in preparation 'Erlotinib monotherapy for the maintenance treatment of non-small-cell lung cancer after previous platinum containing chemotherapy', date of publication TBC.</p> <p>Related Guidelines:</p> <p>Clinical Guideline No. 24. February 2005. Lung cancer: diagnosis and treatment.</p>