

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Necitumumab for untreated advanced, metastatic, squamous non-small-cell lung cancer

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of necitumumab within its marketing authorisation for untreated advanced, metastatic, squamous non-small-cell lung cancer.

Background

Lung cancer falls into two main histological categories: around 85–90% are non-small-cell lung cancers (NSCLC) and the remainder are small-cell lung cancers. NSCLC can be further classified into 3 histological sub-types of large-cell undifferentiated carcinoma, squamous cell carcinoma and adenocarcinoma. Most lung cancers are diagnosed at an advanced stage, when the cancer has spread to lymph nodes and other organs in the chest (locally advanced disease; stage III) or to other parts of the body (metastatic disease; stage IV). In 2013, approximately 26,800 people were diagnosed with NSCLC in England, of whom 13.2% had stage IIIA, 9.4% had stage IIIB and 45.6% had stage IV disease¹.

NICE clinical guideline 121 'Lung cancer' recommends that people with stage III or IV NSCLC and good performance status should be offered chemotherapy to improve survival, disease control and quality of life. NICE clinical guideline 121 recommends a combination of a single third generation drug (docetaxel, gemcitabine, paclitaxel or vinorelbine) plus a platinum drug as an option for people with untreated stage III or IV NSCLC and good performance status. People who are unable to tolerate a platinum combination may be offered single-agent chemotherapy with a third-generation drug (docetaxel, gemcitabine, paclitaxel or vinorelbine).

The technology

Necitumumab (brand name unknown, Eli Lilly) is a fully human monoclonal antibody, which inhibits the epidermal growth factor receptor (EGFR). It is administered by intravenous infusion.

Necitumumab does not currently have a marketing authorisation in the UK for untreated advanced, metastatic, squamous non-small-cell lung cancer. It has been studied in clinical trials in combination with gemcitabine plus cisplatin compared with gemcitabine plus cisplatin in adults with untreated advanced, metastatic, squamous non-small-cell lung cancer.

¹ Cancer Research, Biological therapy for lung cancer

Intervention(s)	Necitumumab in combination with gemcitabine plus cisplatin
Population(s)	People with untreated advanced, metastatic, squamous non-small-cell lung cancer
Comparators	A platinum drug (carboplatin or cisplatin) in combination with: <ul style="list-style-type: none"> • docetaxel • gemcitabine • paclitaxel • vinorelbine
Outcomes	The outcome measures to be considered include: <ul style="list-style-type: none"> • 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	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	Related Technology Appraisals: Appraisals in development (including suspended appraisals) Suspended appraisal. Cetuximab for the treatment of advanced non-small-cell lung cancer. NICE technology appraisals guidance. [ID9] Publication date to be

	<p>confirmed</p> <p>Related Guidelines:</p> <p>The diagnosis and treatment of lung cancer (2011). NICE clinical guideline 121. Review date June 2015</p> <p>Related Quality Standards:</p> <p>Quality standard for lung cancer. (2012). NICE Quality Standard No. 17 http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp</p> <p>Related NICE Pathways:</p> <p>NICE Pathway: Lung cancer. Pathway created: Mar 2012. http://pathways.nice.org.uk/pathways/lung-cancer</p>
<p>Related National Policy</p>	<p>Department of Health (2011) Improving outcomes: a strategy for cancer</p> <p>Department of Health (2009) Cancer commissioning guidance</p> <p>Department of Health (2007) Cancer reform strategy http://www.england.nhs.uk/wp-content/uploads/2014/01/pss-manual.pdf</p> <p>Department of Health, NHS Outcomes Framework 2014-2015, Nov 2013. Domains 1, 2, 4 and 5. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/256456/NHS_outcomes.pdf</p>