

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Proposed Health Technology Appraisal**

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

**Draft scope (pre-referral)**

**Draft 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. 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 disease<sup>1</sup>. People with NSCLC can be either epidermal growth factor receptor (EGFR)-positive or EGFR-negative.

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 platinum-based chemotherapy 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). Afatinib, erlotinib and gefitinib are recommended as options for people who test positive for the epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation and who have not previously received treatment (NICE technology appraisal guidance 310, 258 and 192). Pemetrexed in combination with cisplatin is recommended as an option if the tumour is an adenocarcinoma or large-cell carcinoma (NICE technology appraisal guidance 181).

**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.

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<sup>1</sup> Cancer Research, Biological therapy for lung cancer

Necitumumab does not currently have a marketing authorisation in the UK for treating 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.

<b>Intervention(s)</b>	Necitumumab in combination with gemcitabine plus cisplatin
<b>Population(s)</b>	People with untreated advanced, metastatic, squamous non-small-cell lung cancer
<b>Comparators</b>	Combination of a single drug plus platinum drug (carboplatin or cisplatin): <ul style="list-style-type: none"> <li>• docetaxel</li> <li>• gemcitabine</li> <li>• paclitaxel</li> <li>• vinorelbine</li> </ul>
<b>Outcomes</b>	The outcome measures to be considered include: <ul style="list-style-type: none"> <li>• overall survival</li> <li>• progression-free survival</li> <li>• response rates</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>
<b>Economic analysis</b>	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.
<b>Other considerations</b>	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.

<p><b>Related NICE recommendations and NICE Pathways</b></p>	<p>Related Technology Appraisals:</p> <p>Appraisals in development (including suspended appraisals)</p> <p>Suspended appraisal. Cetuximab for the treatment of advanced non-small-cell lung cancer. NICE technology appraisals guidance. [ID9] Publication date to be confirmed</p> <p>Related Guidelines:</p> <p>The diagnosis and treatment of lung cancer (2011). NICE guideline. Review date June 2015</p> <p>Related Quality Standards:</p> <p>Quality standard for lung cancer. (2012). NICE Quality Standard No. 17  <a href="http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp">http://www.nice.org.uk/guidance/qualitystandards/qualitystandards.jsp</a></p> <p>Related NICE Pathways:</p> <p>NICE Pathway: Lung cancer. Pathway created: Mar 2012. <a href="http://pathways.nice.org.uk/pathways/lung-cancer">http://pathways.nice.org.uk/pathways/lung-cancer</a></p>
<p><b>Related National Policy</b></p>	<p>Department of Health (2013) <a href="#">NHS Outcomes Framework 2014-2015</a></p> <p>Department of Health (2011) <a href="#">Improving outcomes: a strategy for cancer</a></p> <p>Department of Health (2009) <a href="#">Cancer commissioning guidance</a></p> <p>Department of Health (2007) <a href="#">Cancer reform strategy</a>  <a href="http://www.england.nhs.uk/wp-content/uploads/2014/01/pss-manual.pdf">http://www.england.nhs.uk/wp-content/uploads/2014/01/pss-manual.pdf</a></p> <p>Department of Health, NHS Outcomes Framework 2014-2015, Nov 2013. Domains 1, 2, 4 and 5.  <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/256456/NHS_outcomes.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/256456/NHS_outcomes.pdf</a></p>

### Questions for consultation

Have all relevant comparators for necitumumab been included in the scope?

- Which treatments are considered to be established clinical practice in the NHS for advanced, untreated, metastatic, squamous non-small-cell lung cancer?
- 'How should best supportive care be defined?'

Are there any subgroups of people in whom necitumumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider necitumumab will fit into the existing NICE pathway, [lung cancer](#)?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which necitumumab will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider necitumumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of necitumumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome 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/article/pmg19/chapter/1-Introduction>)