

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Nivolumab for previously treated locally advanced or metastatic squamous non-small-cell lung cancer

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of nivolumab within its marketing authorisation for previously treated locally advanced or metastatic 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^{1,2}. NSCLC can be further classified into 3 histological sub-types of large-cell undifferentiated carcinoma, squamous cell carcinoma and adenocarcinoma; about 25–30% of lung cancers are squamous cell carcinomas¹. 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 3551 (13.2%) had stage IIIA, 2527 (9.4%) had stage IIIB and 12,229 (45.6%) had stage IV disease².

Lung cancer caused 28,000 deaths in England in 2012³. The median survival with lung cancer (all stages) is approximately 6 months; 35% of people with lung cancer, and 14% of people with stage IV disease, survive for more than 1 year^{2,3}.

For the majority of people with NSCLC, the aims of therapy are to prolong survival and improve quality of life. NICE clinical guideline 121 (CG121) recommends platinum-based chemotherapy as an option for people with untreated stage III or IV NSCLC and good performance status. CG121 recommends that for people with locally advanced or metastatic NSCLC whose disease has progressed after chemotherapy, docetaxel monotherapy should be considered. Supportive care may be considered for some people for whom. Treatment choices may be influenced by the presence of biological markers (such as mutations in EGFR-TK), histology (squamous or non-squamous) and previous treatment experience; in clinical practice, squamous tumours that have progressed after chemotherapy are usually treated with docetaxel, erlotinib (NICE technology appraisal 162) or supportive care.

The technology

Nivolumab (Nivolumab-BMS, Bristol-Myers Squibb) is a monoclonal antibody that targets a receptor on the surface of lymphocytes known as PD-1. This

receptor is part of the immune checkpoint pathway, and blocking its activity may promote an anti-tumour immune response. Nivolumab is administered by IV infusion.

Nivolumab does not currently have a marketing authorisation in the UK for previously treated locally advanced or metastatic non-small cell lung cancer. It has received a positive opinion from the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) for "the treatment of locally advanced or metastatic squamous non-small cell lung cancer (NSCLC) after prior chemotherapy in adults".

Intervention(s)	Nivolumab
Population(s)	People with previously treated locally advanced or metastatic (stage III or IV) squamous non-small cell lung cancer
Comparators	<ul style="list-style-type: none"> • Docetaxel • Erlotinib (subject to ongoing review of NICE technology appraisal 162) • Best supportive care
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • overall survival • progression-free survival • response rates • adverse effects of treatment • health-related quality of life.
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any patient access schemes for the intervention or comparator technologies should be taken into account.</p>
Other considerations	If the evidence allows, consideration will be given to

	<p>subgroups based on biological markers.</p> <p>If appropriate, the appraisal should include consideration of the costs and implications of additional testing for biological markers, but will not make recommendations on specific diagnostic tests or devices.</p> <p>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>
<p>Related NICE recommendations and NICE Pathways</p>	<p>Related Technology Appraisals:</p> <p>Technology Appraisal No. 162, Nov 2008, 'Erlotinib for the treatment of non-small-cell lung cancer'. Review in progress.</p> <p>Technology Appraisal in preparation, 'Erlotinib and gefitinib for treating non-small-cell lung cancer that has progressed following prior chemotherapy (Review of TA162 and TA175)' [ID620]. Expected date of publication TBC.</p> <p>Related Guidelines:</p> <p>Clinical Guideline No. 121, Apr 2011, 'The diagnosis and treatment of lung cancer'. Review date June 2015</p> <p>Related Quality Standards:</p> <p>Quality Standard No. 17, Mar 2012, 'Quality standard for lung cancer'. 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, Improving Outcomes: A Strategy for Cancer, third annual report, Dec 2013 https://www.gov.uk/government/publications/the-national-cancer-strategy-3rd-annual-report--2</p> <p>NHS England, Manual for prescribed specialised services, service 105: specialist cancer services (adults), Jan 2014. http://www.england.nhs.uk/wp-content/uploads/2014/01/pss-manual.pdf</p> <p>Department of Health, NHS Outcomes Framework 2013-2014, Nov 2013.</p>

	<p>https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/256456/NHS_outcomes.pdf</p> <p>Department of Health, Cancer commissioning guidance, Dec 2009.</p> <p>http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_110115</p>
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References

1. American Cancer Society (2015) [Learn about cancer: What is non-small-cell lung cancer?](#) Accessed June 2015.
2. Health and Social Care Information Centre (2014) [National Lung Cancer Audit: 2013 patient cohort](#). Accessed June 2015.
3. Cancer Research UK (2014) [Lung cancer statistics](#). Accessed June 2015.