NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Liposomal cisplatin in combination with chemotherapy for treating inoperable advanced non-small cell lung cancer

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of liposomal cisplatin in combination with chemotherapy within its licensed indication for inoperable advanced 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. The main types of NSCLC are squamous cell carcinoma (45%), adenocarcinoma (45%) and large cell carcinoma (10%). Between 5% and 15% of people with NSCLC are diagnosed on routine chest radiographic examination, but the majority present with symptoms and signs related either to the site of the growth of the primary tumour, or to the effects of thoracic or metastatic spread. Approximately a third of people with NSCLC present with local potentially resectable disease and about 50% of these will be suitable for surgery. About 30% of people present with locally and regionally advanced disease (Stage IIIb) and 40% with advanced disease (Stage IV in which there are distant metastases or a pleural or pericardial effusion).

In England there were 33,818 people newly diagnosed with lung cancer and 28,166 deaths registered in 2010. The prognosis for people presenting with stage III NSCLC is poor, with a five-year survival rate of approximately 6%. Estimates of the number of people who receive first line chemotherapy for inoperable NSCLC vary between 1320 and 6447 per year. Lung cancer incidence and mortality rates are strongly associated with smoking and socio-economic deprivation.

For people with advanced NSCLC whose disease is inoperable, the aims of therapy are to prolong survival and improve quality of life. Treatment may include radiotherapy and supportive care with or without chemotherapy. NICE clinical guideline No. 121 recommends that on the diagnosis and treatment of lung cancer chemotherapy should be offered to people with stage III or IV NSCLC and a good performance status. This should be a combination of docetaxel, gemcitabine, paclitaxel or vinorelbine plus carboplatin or cisplatin. People who are unable to tolerate a platinum combination may be offered single-agent chemotherapy. NICE technology appraisal guidance No. 181 recommends pemetrexed in combination with cisplatin as an option for the first-line treatment of locally advanced or metastatic NSCLC if the histology of

the tumour has been confirmed as adenocarcinoma or large-cell carcinoma. NICE also recommends gefitinib and erlotinib as options for the first-line treatment of people with locally advanced or metastatic NSCLC if they test positive for the EGFR-TK mutation (NICE technology appraisal guidance No. 192 and No. 258).

The technology

Liposomal cisplatin (Nanoplatin, Regulon) is a new formulation of cisplatin that targets and fuses with human tumour cells allowing for the specific delivery of the cytotoxic drug directly into cancer cells. This reduces the toxicity of cisplatin. In addition, the liposome coating may help the drug to evade the immune system. Liposomal cisplatin is administered by intravenous infusion.

Liposomal cisplatin does not currently have a UK marketing authorisation for treating inoperable advanced NSCLC. It has been studied in clinical trials in combination with pemetrexed or paclitaxel or gemcitabine compared with cisplatin in combination with pemetrexed or paclitaxel or gemcitabine in adults with previously untreated stage IIIB and IV inoperable NSCLC.

Intervention(s)	Liposomal cisplatin in combination with chemotherapy
Population(s)	Adults with previously untreated advanced inoperable non-small cell lung cancer
Comparators	• Established clinical management without liposomal cisplatin
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. The availability of any patient access schemes for the intervention or comparator technologies should be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation or CE marking. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued 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: A combined review proposal is currently underway for: • Technology appraisal No. 192, July 2010. 'Gefitinib for the treatment of non-small cell lung cancer'; • Technology appraisal No. 181, 'Pemetrexed for the first line treatment of non-small-cell lung cancer'; • Technology appraisal No. 190, 'Pemetrexed for the maintenance treatment of non-small-cell lung cancer'; • Technology appraisal No. 227, 'Erlotinib monotherapy for the maintenance treatment of non-small cell lung cancer'; and • Technology appraisal No. 258, 'Erlotinib for the first-line treatment of locally advanced or metastatic EGFR-TK mutation-positive non-small cell lung cancer'. Related Guidelines: Clinical Guideline No. 121, Apr 2011, 'The diagnosis and treatment of lung cancer' (replaces NICE clinical guideline 24). Related Quality Standards: Quality Standard No. 17, Mar 2012, 'Lung cancer for

	adults'. Related NICE Pathways: NICE Pathway: Lung cancer. Pathway created: Mar 2012. http://pathways.nice.org.uk/pathways/lung-cancer
Related national policy	NHS England (2013) Manual for prescribed specialised services (Chapter 18) http://www.england.nhs.uk/wp-content/uploads/2014/01/pss-manual.pdf Department of Health (2011) Improving outcomes: a strategy for cancer Department of Health (2009) Cancer commissioning guidance Department of Health (2007) Cancer reform strategy

Questions for consultation

Which treatments are considered to be established clinical practice in the NHS for advanced inoperable NSCLC?

- Should erlotinib and gefitinib be included as comparators for people with advanced NSCLC who test positive for the epidermal growth factor receptor tyrosine kinase (EGFR-TK) mutation?

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

Where do you consider liposomal cisplatin will fit into the existing NICE Lung cancer pathway?

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 liposomal cisplatin 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 liposomal cisplatin 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 treatment of advanced NSCLC)?

Do you consider that the use of liposomal cisplatin 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/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)