NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Proposed Health Technology Appraisal

Nimotuzumab for the first-line treatment of locally advanced and/or metastatic pancreatic cancer

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of nimotuzumab within its licensed indication for the first-line treatment of locally advanced and/or metastatic pancreatic cancer.

Background

Pancreatic cancer is often symptomless until advanced stages of the disease, meaning curative surgery is often not possible by the time the condition has been diagnosed. Consequently, patients with locally advanced or metastatic disease may be offered chemotherapy, radiotherapy or palliative surgery to help control tumour growth and symptoms. These may be given alone or in combination with each other.

In 2008 there were 8085 new diagnoses of pancreatic cancer in the UK. The most common type of pancreatic cancer is ductal adenocarcinoma, which accounts for up to 95% of cases. Around 75% of people diagnosed with pancreatic cancer are aged 65 years or over. Pancreatic cancer caused 7781 deaths in 2008 in the UK. This high mortality rate is partly due to the high incidence of metastatic disease at diagnosis and the length of time between diagnosis and death is typically less than 6 months. Data for patients diagnosed in England in 2004–2006 show that around 16% survive beyond 12 months and less than 3% survive to 5 years.

'Guidance on the use of gemcitabine for the treatment of pancreatic cancer' (NICE technology appraisal guidance 25) recommends that gemcitabine should be offered as a first-line treatment to patients with advanced or metastatic pancreatic cancer if they have a Karnofsky performance score of 50 or more. It states that there is insufficient evidence to recommend second-line use. Oxaliplatin in combination with irinotecan, fluorouracil and leucovorin (FOLFIRINOX) may also be used off-label for the treatment of locally advanced and/or metastatic pancreatic cancer.

The technology

Nimotuzumab (Theraloc, Oncoscience AG) is an epidermal growth factor antagonist and humanised monoclonal antibody designed to target the epidermal growth factor receptor (EGFR) and inhibit the activation of protein tyrosine kinase. It is administered by intravenous infusion.

Nimotuzumab does not currently have a UK marketing authorisation for the treatment of locally advanced and/or metastatic pancreatic cancer. Nimotuzumab is currently being studied as a first-line treatment in combination with gemcitabine versus gemcitabine and placebo for people with locally advanced and/or metastatic pancreatic cancer.

Intervention(s)	Nimotuzumab in combination with gemcitabine
Population(s)	Adults with locally advanced and/or metastatic pancreatic cancer not previously treated with chemotherapy
Comparators	• Gemcitabine • Gemcitabine plus capecitabine • Oxaliplatin plus irinotecan, fluorouracil and leucovorin (FOLFIRINOX)
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • time to tumour progression • response rate • 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. If evidence allows, the appraisal will consider the following subgroup: people with locally advanced versus metastatic disease.

Related NICE recommendations	Related Technology Appraisals: Technology Appraisal No. 25, May 2001, 'Guidance on the use of gemcitabine for the treatment of pancreatic cancer'. Guidance on static list. Suspended Technology Appraisal 'Capecitabine for the treatment of advanced pancreatic cancer'. Proposed Technology Appraisal, 'Masitinib for the treatment of pancreatic cancer'. Related Cancer Service Guidance: Cancer Service Guidance, March 2004 'Improving supportive and palliative care for adults with cancer'. Related Quality Standards: Quality Standard 'End of life care for adults'.

Questions for consultation

Have the most appropriate comparators for nimotuzumab for the treatment of locally advanced and/or metastatic pancreatic cancer been included in the scope? Are the comparators listed routinely used in clinical practice?

Are the subgroups suggested in 'other considerations appropriate? Are there any other subgroups of people in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately?

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 nimotuzumab 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 the technology 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 the technology 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)