NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Masitinib for treating locally advanced or metastatic pancreatic cancer

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of masitinib within its licensed indication for the treatment of locally advanced or metastatic pancreatic cancer.

Background

In 2010 there were 8463 new diagnoses of pancreatic cancer in the UK. Pancreatic cancer can occur at any age, but tends to affect people aged over 50 years, and is rare among younger people. Around 75% of people diagnosed with pancreatic cancer are aged 65 years or over. Men tend to be more affected than women, and people who smoke or have diabetes or chronic pancreatitis are also at higher risk. There were around 7900 deaths due to pancreatic cancer in 2010 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 2005–2009 show that less than 20% survive beyond 12 months and less than 4% survive to 5 years.

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, people 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.

NICE technology appraisal no. 25 recommends gemcitabine as a first-line treatment for people with advanced or metastatic pancreatic cancer if they have a Karnofsky performance score of 50 or more. In clinical practice, capecitabine is often used off-label in combination with gemcitabine. Oxaliplatin in combination with irinotecan, fluorouracil and folinic acid (FOLFIRINOX) is also used off-label for treating metastatic pancreatic cancer.

The technology

Masitinib (Masiviera, AB Science) is a tyrosine kinase inhibitor that inhibits c-kit (mast cell growth factor receptor), platelet-derived growth factor receptor, fibroblast growth factor receptor and kinases that are involved in cell proliferation and resistance to chemotherapy. Masitinib is administered orally.

Masitinib does not currently have a UK marketing authorisation for the treatment of advanced or metastatic pancreatic cancer. It has been studied in

clinical trials in combination with gemcitabine compared with gemcitabine plus placebo in adults with advanced or metastatic adenocarcinoma of the pancreas who have not previously received chemotherapy.

Intervention(s)	Masitinib plus gemcitabine
Population(s)	Adults with locally advanced or metastatic adenocarcinoma of the pancreas that has not been previously treated with chemotherapy
Comparators	• Gemcitabine • Gemcitabine plus capecitabine • Oxaliplatin plus irinotecan, fluorouracil and folinic acid (FOLFIRINOX)
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • 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 following subgroups will be considered: locally advanced versus metastatic disease; level of pain; presence or absence of biomarkers that could identify which patients are likely to experience a greater benefit of treatment.

Related NICE recommendations and NICE pathways	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, 'Nimotuzumab for the treatment of pancreatic cancer'. Publication TBC. Proposed Technology Appraisal, 'Paclitaxel formulated as albumin-bound nanoparticles in combination with gemcitabine for previously untreated advanced pancreatic cancer'. Publication TBC. 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'.
Related NHS England policy	None