NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Imatinib for the adjuvant treatment of gastrointestinal stromal tumours (review of TA196)

Draft scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of imatinib within its licensed indication for the adjuvant treatment of gastrointestinal stromal tumours

Background

Gastrointestinal stromal tumours (GISTs) are rare connective tissue tumours. Although GISTs can occur along the length of the GI tract, the majority arise in the stomach (60–70%) or small intestine (25–35%). GISTs are associated with the overexpression of several tyrosine kinase growth receptors and the ligands that bind to them. Around 75–80% of GISTs have activating mutations in c-KIT (CD117), a tyrosine kinase receptor, and 5–10% in platelet-derived growth factor receptor-alpha. These factors are thought to be important in driving tumour development.

The annual incidence of GIST is estimated to be approximately 900 new diagnoses per year in the UK and approximately half of these are likely to be resectable. Although GISTs can occur at any age, mean age at presentation is 50–70 years and it is more common in men than women.

Complete surgical excision is the current standard treatment for localised GISTs. Recurrence occurs in 40–50% of patients who have had complete resection and the survival rates after complete resection are 88% at 1 year and 54% at 5 years. NICE technology appraisal guidance 196 does not recommend imatinib for the adjuvant treatment of GISTs after surgery, and watchful waiting is the current standard of care.

The technology

Imatinib (Glivec, Novartis Pharmaceuticals) is a selective kinase inhibitor. Imatinib binds to activated c-KIT receptors and blocks the cell signalling pathway, preventing uncontrolled cell proliferation. Imatinib is administered orally.

Imatinib has a UK marketing authorisation for the ‘adjuvant treatment of adult patients who are at significant risk of relapse following resection of KIT (CD117)-positive GISTs. Patients who have a low or very low risk of recurrence should not receive adjuvant treatment’.

Intervention(s)	Imatinib as an adjuvant therapy after surgery
Population(s)	Adults who are at significant risk of relapse following resection of KIT (CD117)-positive GIST
Comparators	Surgery without adjuvant therapy
Outcomes	The outcome measures to be considered include: • overall survival • recurrence-free survival • 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	If evidence allows, subgroup analyses by baseline risk of relapse and tumour genetic mutational status should be considered. Consideration should be given to number of treatment cycles and continuation rules for treatment if clinically appropriate. Guidance will only be issued in accordance with the marketing authorisation.
Related NICE recommendations	Related Technology Appraisals: Technology Appraisal No. 196, August 2010, 'Imatinib for the adjuvant treatment of gastrointestinal stromal tumours'. Currently under review. Related Cancer Service Guidance: Cancer Service Guidance, March 2006 'Improving outcomes for people with sarcoma' Cancer Service Guidance, March 2004 'Improving supportive and palliative care for adults with cancer'

Questions for consultation

Have the most appropriate comparators for imatinib for the adjuvant treatment of GIST been included in the scope?

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 imatinib is 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