

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

Health Technology Appraisal

Imatinib for gastrointestinal stromal tumours

Scope

Objective: to establish the clinical and cost effectiveness of imatinib in the treatment of KIT positive, metastatic and/or unresectable gastro-intestinal stromal tumours (GISTs), relative to current standard treatments, and to produce guidance to the NHS in England and Wales.¹

Background: Gastro-intestinal stromal tumours (GISTs) are a rare type of sarcoma arising from precursors of the connective tissue of the digestive system (most frequently in the stomach), associated with the over-expression of KIT (CD117), a tyrosine kinase receptor, which is thought to promote tumour growth or to inhibit tumour cell death via a signal transduction pathway.

Incidence is estimated to be between 4 - 6 cases per million (which would correspond to a figure of between 208 – 312 new cases a year in England and Wales). However, a recent study from Sweden found that GIST has been under-diagnosed, and suggested that the incidence could be as high as 16/million population².

The standard treatment is surgery for resectable GISTs. There is currently no effective treatment for surgically unresectable or metastatic GIST, and the response rates to conventional chemotherapeutic agents are reported to be less than 5%. People with advanced or metastatic GIST are offered symptom relief and supportive care.

The technology: Imatinib (Glivec, Novartis) is an oral signal transduction inhibitor that inhibits the tyrosine kinase receptor KIT. It is licensed for the treatment of adult patients with KIT (CD 117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumours.

Intervention(s)	Oral imatinib
Population(s)	People with KIT (CD 117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumours

Current standard treatments (comparators)	Treatment of people with unresectable and/or metastatic GISTs currently comprises symptom-relief and best supportive care.
Other considerations:	<p>Survival and 'quality of life' are preferred end-points in terms of assessing effectiveness. However surrogate outcome measures will be considered, given that the association with survival has been clearly demonstrated.</p> <p>If the evidence allows, the appraisal will attempt to identify the criteria for selecting patients for whom this treatment would be particularly appropriate.</p>

¹ The remit from the Department of Health/National Assembly for Wales is "To appraise the clinical and cost effectiveness of imatinib in its licensed indication for treatment of gastrointestinal stromal tumours"

² Kindblom LG, et al. (2002) *Incidence, prevalence, phenotype and biologic spectrum of gastrointestinal stromal cell tumours (GIST): a population based study of 600 cases*. Abstract Book of the 27th ESMO Congress, Nice, France, 18-22 October 2002, Annals of Oncology 13 (Suppl 5) Abstract 577.