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Quick reference guide

Imatinib for the treatment of unresectable and/or metastatic gastro-intestinal stromal tumours

1 Guidance

- 1.1 Imatinib treatment at 400 mg/day is recommended as first-line management of people with KIT (CD117)-positive unresectable and/or KIT (CD117)-positive metastatic gastro-intestinal stromal tumours (GISTs).
- 1.2 Continuation with imatinib therapy is recommended only if a response to initial treatment (as defined in Section 1.5) is achieved within 12 weeks.
- 1.3 Responders should be assessed at intervals of approximately 12 weeks thereafter. Continuation of treatment is recommended at 400 mg/day until the tumour ceases to respond, as defined in Section 1.5.
- 1.4 An increase in the dose of imatinib is not recommended for people receiving imatinib who develop progressive disease after initially responding (see Section 1.5).
- 1.5 For the purpose of this guidance, response to imatinib treatment should be assessed on the basis of the results of diagnostic imaging to assess size and density of the tumour(s), patients' symptoms and other factors, in accordance with the Southwest Oncology Group (SWOG) criteria detailed in the full guidance (see www.nice.org.uk/TA086guidance). For the purpose of this guidance, response to therapy is defined as the SWOG classifications of complete response, partial response or stable disease.
- 1.6 The use of imatinib should be supervised by cancer specialists with experience in the management of people with unresectable and/or metastatic GISTs.

2 Implementation

2.1 Implications for the NHS

- 2.1.1 The cost impact of this guidance will depend on: the number of patients with unresectable and/or metastatic GIST; the proportion who receive imatinib; the proportion who respond to imatinib; duration of treatment; price of imatinib; and the number of patients already prescribed imatinib for GIST.
- 2.1.2 Estimates of the annual incidence of GIST vary considerably, and may be underestimates; figures may increase as more tumours are tested for c-KIT. The manufacturer of imatinib estimated the number of new cases of unresectable and/or metastatic GIST to be between 80 and 240 each year. The annual drug cost of imatinib is just under £19,000. Assuming 240 new patients eligible for imatinib treatment for GIST, monitored by an average of four CT scans per year, the total cost of treating new patients in accordance with the guidance will be approximately £4.7 million in the first year. Assuming that the incidence does not change and patients remain on imatinib treatment for an average of 1.44 years, the total cost of treating patients with imatinib for GIST will be approximately £6.8 million when the number of patients receiving imatinib reaches a steady state.
- 2.1.3 The resource impact for the NHS will depend on the number of patients currently receiving NHS prescriptions for imatinib for the treatment of GIST. Using the assumptions set out above, if 25% of eligible patients currently receive NHS prescriptions for imatinib for GIST, the additional cost of implementing this guidance will be approximately £5.1 million. If 75% of eligible patients are currently being treated with imatinib, the impact of the guidance will be about £1.7 million. These amounts could be much less if switching to

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This guidance is written in the following context:

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

higher doses of imatinib is reduced or if GIST patients receive imatinib treatment rather than inappropriate surgery or chemotherapy.

2.2 Local implementation and audit

- 2.2.1 All clinicians who treat people with KIT (CD117)-positive unresectable and/or KIT (CD117)-positive metastatic GIST should review their current policies and practice to take account of the guidance set out in Section 1.
- 2.2.2 Local guidelines or care pathways for the care of patients with KIT (CD117)-positive unresectable and/or KIT (CD117)-positive metastatic GIST should incorporate the guidance.
- 2.2.3 To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in the full guidance.
- For a person with KIT (CD117)-positive unresectable and/or KIT (CD117)-positive metastatic GIST, imatinib treatment at

400 mg/day is provided as first-line management for up to 12 weeks.

- Imatinib therapy at 400 mg/day is continued beyond 12 weeks only if the GIST responds within 12 weeks. (Response to treatment is defined in Section 1.5 above and in the full guidance.)
- A person whose GIST has responded to imatinib therapy is assessed at intervals of approximately 12 weeks and imatinib therapy at 400 mg/day is continued until the GIST ceases to respond.
- If progressive disease develops in a person whose GIST initially responded to imatinib therapy, the dose of imatinib is not increased.
- A cancer specialist with experience in the management of people with metastatic and/or unresectable GISTs supervises the use of imatinib.

2.2.4 Further details on criteria for audit are included in the full guidance (see Further Information).

Further information

Distribution

The distribution list for this quick reference guide is available on the NICE website at www.nice.org.uk/TA086distributionlist

Full guidance

The full guidance is available from www.nice.org.uk/TA086guidance

It contains the following sections: 1 Guidance; 2 Clinical need and practice; 3 The technology; 4 Evidence and interpretation; 5 Recommendations for further research; 6 Implications for the NHS; 7 Implementation and audit; 8 Related guidance; 9 Review of guidance.

The full guidance also gives details of the Appraisal Committee, the sources of evidence considered and suggested criteria for audit.

Information for the Public

NICE has produced information describing this guidance for people with unresectable and/or metastatic gastro-intestinal stromal tumours, their families, and the public. This information is available from the NHS Response Line and from the NICE website (www.nice.org.uk/TA086publicinfo).

Related guidance

All issued guidance and details of appraisals and guidelines in progress are available on the NICE website (www.nice.org.uk)

- Guidance on the use of imatinib for chronic myeloid leukaemia. *NICE Technology Appraisal Guidance No. 70*. (see www.nice.org.uk/TA70guidance)

Ordering information

Copies of this quick reference guide can be obtained from the NICE website at www.nice.org.uk/TA086quickrefguide or from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0552. 'Information for the public' can be obtained by quoting reference number N0553 for the English version and N0554 for a version in English and Welsh.

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