



National Institute for Health and Clinical Excellence

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PRESS RELEASE

Insufficient new evidence on increased doses of imatinib for treating GISTs

NICE has been unable to recommend imatinib (Glivec) at increased doses to treat gastrointestinal stromal tumours (GISTs), when standard doses have stopped working, due to insufficient new evidence.

This appraisal is a part review of NICE technology appraisal guidance 86 (TA86) on the use of imatinib to treat unresectable and/or metastatic GISTs. The Committee was asked to look at dose increases of imatinib after disease progression on 400 mg/day imatinib only. This guidance updates recommendation 1.4 of TA86, all other recommendations in TA86 still stand.

NICE has previously recommended imatinib at a dose of 400 mg/day to treat GISTs that cannot be removed by surgery¹ and also recommends sunitinib (Sutent) for patients for whom treatment of GISTs with imatinib has not worked or is not suitable². This review looked specifically at increased doses of imatinib after treatment with 400 mg/day imatinib has stopped working. The increased doses of imatinib being considered were 600 mg/day and 800 mg/day.

NICE Chief Executive, Sir Andrew Dillon said: "NICE already currently recommends imatinib at a dose of 400 mg/day to treat GISTs that cannot be removed by surgery. In our previous appraisal we did not recommend an increased dose of imatinib after disease progression on 400 mg/day imatinib, but we wanted to review any new evidence to see whether increased doses could be justified. The independent Appraisal Committee found that since the original guidance was published in October 2004, there have been no new good quality clinical and cost

¹ NICE technology appraisal guidance 86

² NICE technology appraisal guidance 179

effectiveness data produced on doses of 600 or 800 mg/day imatinib given after disease progression on a dose of 400 mg/day³. On this basis, we cannot recommend these higher doses of imatinib for use on the NHS.”

Ends

Notes to Editors

About the guidance

1. The guidance will be available on the NICE website from 24 November at - www.nice.org.uk/guidance/TA209.
2. GISTs are rare tumours which occur predominantly in the stomach or bowel. Many of these tumours can be removed by surgery but some cannot (unresectable tumours). Without treatment unresectable GISTs progress and will eventually metastasise.
3. The annual incidence of GISTs is estimated to be 14.5 per million population which equates to approximately 791 new cases per year in England and Wales (mid-2008 population). Of these two thirds are considered to be resectable (from the manufacturer's submission).
4. If a daily dose of 400mg/day imatinib was given for a year, the drug cost would be approximately £19,500 per patient, for 600mg/day approximately £29,300 and £39,067 for 800 mg/day.

About NICE

5. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
6. NICE produces guidance in three areas of health:
 - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
 - **health technologies** – guidance on the use of new and existing medicines, treatments and procedures within the NHS
 - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

³ The limited available data was used to try and establish the cost effectiveness of increased doses of imatinib given after disease progression on 400 mg/day imatinib, and the results have led the Committee to conclude that increased doses of imatinib are not an appropriate use of NHS resources for people with unresectable and/or metastatic GIST whose disease has progressed after taking 400 mg/day imatinib.