

Imatinib for gastro-intestinal stromal tumours

**Understanding NICE guidance –
information for adults with
gastro-intestinal stromal tumours,
and the public**

October 2004



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Understanding NICE guidance – information for adults with gastrointestinal tumours, and the public

Issue date: October 2004

Review date: October 2007

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Web: www.nice.org.uk

ISBN: 1-84257-616-X

Published by the National Institute for Clinical Excellence
October 2004

Typeset by Icon Design, Eton
Printed by Oaktree Press Ltd, London

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What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is part of the NHS. It produces guidance (recommendations) on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures within the NHS in England and Wales.

To produce this guidance, NICE looks at how well the medicine, equipment or procedure works and also how well it works in relation to how much it costs. This process is called an appraisal. The appraisal process involves the manufacturer of the medicine or equipment for which guidance is being produced and the organisations that represent the healthcare professionals, patients and carers who will be affected by the guidance.

NICE was asked to look at the available evidence on the use of a medicine called imatinib to treat a rare type of tumour that affects the stomach and bowel, called a gastro-intestinal stromal tumour. NICE was asked to provide guidance that will help the NHS in England and Wales decide when imatinib should be used.

What is a gastro-intestinal stromal tumour?

A gastro-intestinal tumour is one that occurs in the stomach or bowel. A tumour results from the new growth of body tissues that can be benign (non-cancerous) or malignant (a cancer).

Gastro-intestinal stromal tumours (sometimes called gastro-intestinal soft tissue sarcomas) are a rare kind of gastro-intestinal tumour. Many of these tumours are benign, and these usually cause few symptoms. If they become malignant and are confined to one area of the stomach or bowel, they can often be removed surgically. However, some malignant gastro-intestinal stromal tumours can grow too large to be removed by surgery, and they may also spread to other parts of the body.

One of the tests used to diagnose gastro-intestinal stromal tumours looks for a substance called c-KIT on the cancer cells. Tumours with c-KIT are called KIT-positive tumours.

What is imatinib?

Imatinib is a drug that has been developed to treat gastro-intestinal stromal tumours that cannot be removed by surgery, or have spread to other parts of the body. It works by blocking the processes that allow the tumour cells to grow and multiply. This slows down or stops the growth and spread of the tumour.

What has NICE recommended on imatinib?

During the appraisal, NICE's Appraisal Committee read and heard evidence from:

- high-quality studies of imatinib
- doctors with specialist knowledge of gastro-intestinal tumours and their treatment
- individuals with specialist knowledge of the issues affecting people with gastro-intestinal tumours
- the manufacturers of imatinib
- a number of professional/specialist and patient/carer groups.

A number of professional bodies were also asked to comment on the appraisal.

The evidence is summarised in the full guidance (see end for details). More information about the studies is provided in the Assessment Report for this appraisal (see end for details).

NICE has made the following recommendations about the use of imatinib to treat gastro-intestinal stromal tumours within the NHS in England and Wales.

Imatinib is recommended at a dose of 400 mg a day as the first choice of treatment for people who have a gastro-intestinal stromal tumour that is KIT-positive, and cannot be removed surgically or has spread to other parts of the body.

The treatment is given at first for 12 weeks. The patient's healthcare team then assesses whether the treatment is working (if it is, doctors may say the tumour is 'responding to treatment'). To do this, they use CT scans and other tests to look at the size of the tumour, and also take into account the patient's symptoms.

If the treatment is not working after this time, it should be stopped. If the tumour responds to treatment with imatinib, the patient should be reassessed about every 12 weeks until no further benefit from treatment can be detected. When this happens, the treatment should be stopped.

The dose of 400 mg a day should not be increased if the disease starts to get worse, even if the tumour initially responded to treatment.

Treatment with imatinib should be overseen by a cancer specialist with experience in treating patients who have gastro-intestinal stromal tumours that cannot be removed or have spread elsewhere in the body.

What should I do next?

If you or someone you care for has a gastro-intestinal stromal tumour, you should discuss this guidance with your GP or the specialist in charge of the case.

Will NICE review its guidance?

Yes. The guidance will be reviewed in October 2007.

Further information

The NICE website (www.nice.org.uk) has further information about NICE and the full guidance on using imatinib for gastro-intestinal stromal tumours that has been issued to the NHS. The assessment report, which contains details of the studies that were looked at, is also available from the NICE website. A short version of the guidance (a 'quick reference guide') is available on the website and from the NHS Response Line (phone 0870 1555 455 and quote reference number N0552).



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