National Institute for Health and Clinical Excellence

Level One
City Tower
Piccadilly Plaza
Manchester
M1 4BD

Tel: 0845 003 7781

www.nice.org.uk

Mr Kris Griffin
10 Selba Drive
Kidderminster
DY11 6HW

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Our ref: EH21768

Dear Mr Griffin

Sir Andrew Dillon has asked me to thank you for your letter to NICE and to respond on his behalf.

I appreciate that this is a matter of the utmost importance to you and that your diagnosis and subsequent treatment has been very traumatic for you and your family. Although I am unable to comment on your personal clinical circumstances I hope that the following is helpful.

As you are aware our final guidance published in April 2012 recommends the use of nilotinib and standard dose imatinib for the first line treatments of Chronic Myeloid Leukaemia (CML) (guidance ref TA251). This guidance reaffirms the use of imatinib as an effective treatment at a cost which is an effective use of NHS resources and provides a further treatment option for these patients of nilotinib. With regard to our recommendations on dasatinib, the independent Appraisal Committee concluded that both dasatinib and nilotinib could be considered equally effective in treating CML. Both of these drugs incur equal cost per patient per year and standard dose imatinib costs slightly less, however the manufacturer of nilotinib has reached agreement with the Department of Health to provide the drug to the NHS at a discounted price. This reduction in cost enabled the Committee to approve nilotinib for use on the NHS. You can read more about our consideration of the evidence in the appraisal consultation document which is on our website here:
http://guidance.nice.org.uk/TA/Wave24/15/Consultation/Latest

Earlier in the year we published another technology appraisal which recommends nilotinib for the treatment of the chronic and accelerated phases of CML that is resistant or intolerant to standard-dose imatinib, however this guidance does not recommend dasatinib for the treatment of CML that is resistant or intolerant to standard-dose imatinib and high dose imatinib is not recommended for CML that is resistant to standard-dose imatinib. The reference number for this guidance is TA241. I can confirm that, once again the manufacturer submitted a patient access scheme which reduced the cost and therefore enabled the Committee to make a positive recommendation. CML is classed as a chronic condition, meaning that the drugs will be used for a long period of time. In this case Dasatinib and high-dose imatinib did not provide enough benefit to patients to justify their high cost, so NICE did not recommend them.

Patient Access Schemes are negotiated with the manufacturer by the Department of Health. On this occasion the manufacturer has asked that both Patient Access Schemes remain confidential.

It is important to note that our appraisal process is designed to produce robust evidence based recommendations for the NHS that take into account both the clinical and cost-effectiveness of a technology so we look at how well treatments work, and also at how well they work in relation to how much they cost the NHS.

Since 2000, when NICE started to produce cancer guidance, NICE has published 134 individual recommendations on cancer drugs in 89 technology appraisals. Overall, 66% of all recommendations stated that the NHS should use these drugs in line with their marketing authorisation ('recommended'), or in specific circumstances ('optimised recommendation').

The decisions about whether to recommend drugs or treatment are made by independent committees who discuss the evidence and make decisions about a particular health topic. The people on the committees have a wide range of backgrounds. There are professionals including surgeons, GPs, research and social care advisers and members of the public, including patients and people working in charities. Each committee members is carefully selected to ensure that there is a good mix of skills and experience relevant to the particular topic.

We appreciate that our recommendations will come as a disappointment to people living with this condition, as well as those who care for, and who treat them. NICE has to make some of the most difficult decisions in public life. We are aware that cancer is a devastating disease for the individual and their family. Deciding which treatments to recommend involves balancing the needs and wishes of individuals and the groups representing them against those of the wider population. This sometime means treatments are not recommended because they do not provide sufficient benefit to justify their cost.

I hope my reply goes some way to explain the rationale behind our decisions.

Yours sincerely,

Janet Fahie
<u>Enquiry Handling team</u>