

PRESS RELEASE

NICE appraisal of dasatinib and nilotinib for chronic myeloid leukaemia

The National Institute for Health and Clinical Excellence (NICE) has updated its draft guidance on the use of dasatinib (Sprycel, made by Bristol Myers-Squibb) and nilotinib (Tasigna, made by Novartis) for chronic myeloid leukaemia.

Following the previous public consultation and subsequent independent Appraisal Committee meeting on 13 January 2010, both NICE and the appraisal committee agreed to split the appraisal of dasatinib and nilotinib for chronic myeloid leukaemia into two separate appraisals.

To effectively appraise a new treatment, the Committee compares it to an existing one. In this case, high dose imatinib (glivec, 600 mg or 800 mg per day) has been identified as a comparator for dasatinib and nilotinib for people who are 'resistant' to imatinib (standard treatment with imatinib (400 mg per day) has stopped working), although it clearly cannot be a comparator for people who cannot tolerate imatinib.

NICE is about to start a review of its current guidance on high dose imatinib for chronic myeloid leukaemia (TA70), so this review will now incorporate an appraisal of dasatinib and nilotinib compared with high dose imatinib for people who are 'resistant' to standard imatinib treatment. The current appraisal will continue for 'imatinib intolerant' people only.

Also in response to comments received during public consultation the Assessment Group carried out additional analyses addressing the issues raised concerning the cost-effectiveness modelling, and these further analyses were discussed by the Committee. This additional evidence and its consideration by the Committee now needs to be viewed by consultees, therefore a second Appraisal Consultation Determination (ACD), or first draft, has been issued for further consultation.

In its latest draft, issued for public consultation today (9 February 2010), NICE does not recommend dasatinib and nilotinib for chronic myeloid leukaemia in patients who are intolerant to imatinib.

Professor Peter Littlejohns, Clinical and Public Health Director at NICE said:

“The Committee heard from clinical specialists that in their opinion dasatinib and nilotinib are clinically effective. However, the evidence available to support this was very poor, with no studies comparing either drug to other treatments. The cost of the drugs is also extremely high and before committing limited NHS resources to fund them, we need to be sure they are effective. It would be heartening to hear that the pharmaceutical company manufacturers are prepared to share some of the very high cost of the drugs with the NHS.”

These draft recommendations are now open to public consultation, and the manufacturers have been given the opportunity to provide further evidence for the independent committee to consider at its next meeting, on 9 March 2010. Following this meeting the next draft guidance will be issued.

Until NICE issues final guidance, NHS bodies should make decisions locally on the funding of specific treatments. Once NICE issues its guidance on a technology it replaces local recommendations across the country.

Ends

For more information call the NICE press office on 0845 003 7782

Notes to Editors

About the guidance

1. Chronic myeloid leukaemia is a very rare condition that affects around 560 people in the UK each year. Many are treated with a drug called imatinib. If this treatment does not work, the current options are an increased dose of imatinib or a bone marrow transplant.
2. High dose imatinib has been identified as a comparator for dasatinib and nilotinib for people who are ‘resistant’ to imatinib. However, the evidence on high dose imatinib needs to be reviewed. Therefore a review of the current NICE guidance of imatinib for chronic myeloid leukaemia (TA70) will incorporate dasatinib and nilotinib for people who are ‘resistant’ to imatinib. The review is due to start shortly and an updated draft scope for consultation will be issued to include all three treatments
3. Information on the NICE appraisal of dasatinib and nilotinib for the treatment of chronic myeloid leukaemia and the consultation documents are available at <http://guidance.nice.org.uk/TA/Wave17/18>.
4. Independent Evidence Review Groups (ERGs) are charged with the task of critically appraising the manufacturer’s submission and to identify strengths, weaknesses and gaps in the evidence presented. The resultant report is then considered as a part of the evidence considered by the appraisal committee.
5. Comments on the analysis received during public consultation included:

- a. accounting for costs in the post-progression chronic-phase state to reflect treatments that would likely be offered following discontinuation of the technologies under simulation, but prior to disease transformation (accelerated-phase);
 - b. adjusting the assumed dose intensity of high-dose imatinib treatment to approximate reported doses in the study from which effectiveness and treatment duration data has been drawn;
 - c. correcting the calculation of time to progression for the proportion of patients discontinuing treatment prematurely.
6. The acquisition cost of dasatinib is £83.50 per 100 mg tablet. The cost of dasatinib treatment is £30,477.50 per year.
 7. The acquisition cost of nilotinib is £21.72 per 200 mg tablet. The cost of nilotinib treatment is £31,711.20 per year.

About NICE

8. 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.
9. 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.