NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA70; Guidance on the use of imatinib for chronic myeloid leukaemia, and TA251; Dasatinib, nilotinib and standard-dose imatinib for the first line treatment of chronic myeloid leukaemia

This guidance was issued in October 2003 (TA70) and April 2012 (TA251).

The review date for TA251 is May 2014. In July 2009, the decision was made to update TA70. Recommendation 1.1 from TA70 has been updated by TA251. Recommendation 1.3 from TA70 has been updated by TA241 (January 2012).

Background

At the GE meeting of 12 August 2014 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	The guidance should be transferred to the 'static guidance list'.
Rationale for selecting this proposal	The new follow-up data is unlikely to lead to a change in the recommendations of the original guidance. There are currently no changes in the costs of these drugs, and generic imatinib will not be available for some time. Therefore we propose that the guidance should be transferred to the 'static guidance list'.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	The guidance should be transferred to the 'static guidance list'.

Respondent	Response to proposal	Details[1]	Comment from Technology Appraisals
Pfizer	Agree	Pfizer agrees with NICE's proposal to move TA64 to the static list of technology appraisals. We are not aware of any new evidence that would lead to a change in the existing recommendations in TA251 and the remaining recommendations made in TA70 as per your email below.	Response noted.
GlaxoSmithKline	Request change to matrix of stakeholders	Please note that busulphan and mercaptopurine are now owned by Aspen, therefore GlaxoSmithKline should be removed from the comparator manufacturer list, and Aspen added.	Response noted - GlaxoSmithKline has been removed from the comparator manufacturer list, and Aspen added.

[1] Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Respondent	Response to proposal	Details[1]	Comment from Technology Appraisals
Novartis Pharmaceuticals	Agree	Novartis agrees with NICE's approach to refer both TA251 and the remaining recommendations made in TA70 to the static list of technology appraisals. There is currently no available evidence that would lead to a change in the existing recommendations.	Response noted.
Bristol-Myers Squibb	Agree	We agree with the proposal to move this MTA to the static list.	Response noted.
Napp Laboratories	Agree	We have reviewed the documents included with the invitation to comment. We have nothing further to add and would therefore support NICE's intention to move the existing guidance as stated.	Response noted.
National Cancer Research Institute Royal College of Physicians Royal College of Radiologists Association of Cancer	Agree (with caveats)	• While our experts are disappointed that dasatinib is not available in the UK for first-line use (except in the SPIRIT2 trial which has now closed), they agree that there is insufficient new data to recommend it over either imatinib or nilotinib in first line. • There are some concerns emerging regarding potential vascular toxicities with nilotinib. However, at present, data is insufficient to suggest a change and certainly, in terms of efficacy nilotinib is superior to imatinib with higher rates of complete cytogenetic response and major molecular response and fewer progressions to advanced phase disease,	Response noted. Topics on the static list can be considered for review if any new evidence becomes available that is likely to lead to a change in the existing recommendations. The recommendations for imatinib would be unlikely to change when the patent expires and this would also be unlikely to affect the recommendations for dasatinib and nilotinib.

Respondent	Response to proposal	Details[1]	Comment from Technology Appraisals
Physicians		although has yet to translate into a demonstrable improvement in overall survival. Dasatinib and nilotinib have very similar rates of complete cytogenetic response and major molecular response. • Our experts believe it will be important to re-visit the guidance once imatinib is off patent in 2016 and review the data on bio-similar imatinib compounds at that time. It is possible there may be more data emerging about vascular risk and toxicity with nilotinib by then as well. • The other important issue which may change recommendations is the proportion of patients with a sustained complete molecular response that may be able to discontinue therapy. It is possible that the proportion of patients falling into this category may be higher with second generation TKIs such as dasatinib and nilotinib, but further data are required to confirm this hypothesis. This data may be available in the next 2-3 years.	
Royal College of Nursing	No comment	The Royal college of Nursing have no comments to submit to inform on the above review consultation.	Response noted.

No response received from:

Patient/carer groups • Afiya Trust • African Caribbean Leukaemia Trust • Anthony Nolan • Black Health Agency • Cancer Black Care • Cancer Equality • Cancer52 • Chronic Myeloid Leukaemia Support Group • Equalities National Council • HAWC • Helen Rollason Cancer Charity • Independent Cancer Patients Voice • Leukaemia Cancer Society • Leukaemia CARE • Macmillan Cancer Support • Maggie's Centres • Marie Curie Cancer Care • Muslim Council of Britain • Muslim Health Network • Rarer Cancers Foundation • South Asian Health Foundation • Specialised Healthcare Alliance • Tenovus Professional groups • British Committee for Standards in Haematology • British Geriatrics Society	General • Allied Health Professionals Federation • Board of Community Health Councils in Wales • British National Formulary • Care Quality Commission • Department of Health, Social Services and Public Safety for Northern Ireland • Healthcare Improvement Scotland • Medicines and Healthcare Products Regulatory Agency • National Association of Primary Care • National Pharmacy Association • NHS Alliance • NHS Commercial Medicines Unit • NHS Confederation • Scottish Medicines Consortium Comparator manufacturers • AAH Pharmaceuticals (cytarabine, dexamethasone and vincristine sulphate) • Alliance Pharmaceuticals (prednisolone) • Amdipharm (prednisolone) • Aspen (busulphan, mercaptopurine) • Baxter Healthcare (cyclophosphamide) • Bristol-Myers Squibb (hydroxycarbamide) • Cephalon (doxirubicin) • Genus Pharmaceuticals (vincristine) • Hospira UK (cytarabine, cyclophosphamide, dexamethasone, doxorubicin, and vincristine sulphate)

• British Institute of Radiology • British Psychosocial Oncology Society • British Society for Haematology • Cancer Research UK • Royal College of General Practitioners • Royal College of Pathologists • Royal Pharmaceutical Society • Royal Society of Medicine • Society and College of Radiographers • UK Health Forum • United Kingdom Clinical Pharmacy Association • United Kingdom Oncology Nursing Society <u>Others</u> • Department of Health • NHS England • NHS North Durham CCG • NHS Stockport CCG • Welsh Government	• Lilly UK (vincristine sulphate) • Medac UK (hydroxycarbamide) • Merck Sharp and Dohme (dexamethasone and IFN- α) • Nordic Pharma (hydroxycarbamide) • Roche Products (IFN-α) • Rosemont Pharmaceuticals (dexamethasone) • Unichem (cytarabine, vincristine sulphate) • Waymade Healthcare (hydroxycarbamide, mercaptopurine, prednisolone) • Zentiva UK (daunorubicin) <u>Relevant research groups</u> • Cochrane Haematological Malignancies Group • Elimination of Leukaemia Fund • Health Research Authority • Institute of Cancer Research • Leuka • Leukaemia & Lymphoma Research • Leukaemia Busters • MRC Clinical Trials Unit • National Cancer Research Network • National Institute for Health Research <u>Assessment Group</u> • Assessment Group tbc • National Institute for Health Research Health Technology Assessment Programme <u>Associated Guideline Groups</u> • National Collaborating Centre for Cancer

	<u>Associated Public Health Groups</u> • Public Health England • Public Health Wales NHS Trust

GE paper sign-off: Elisabeth George, Associate Director – Technology Appraisals Programme

Contributors to this paper:

Technical Lead: Chris Chesters

Project Manager: Andrew Kenyon

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