NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA61; Capecitabine and tegafur uracil for metastatic colorectal cancer, and TA176; Cetuximab for the first line treatment of metastatic colorectal cancer

This guidance was issued May 2003 (TA61) and August 2009 (TA176) with a review date of August 2012 (TA176). TA61 is currently on the list of static guidance and therefore does not have a specified review date

Background

At the GE meeting of 5 April 2011 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:	TAs 61 and 176 should be incorporated and cross-referenced in the on-going clinical guideline respectively.
Rationale for selecting this proposal	For TA61, there have been licence extensions for capecitabine in its use in metastatic colorectal cancer in that it is now licensed 1st line in combination therapy with oxaliplatin or irinotecan (with or without bevacizumab) and 2nd line in combination therapy with oxaliplatin. However, Topic Selection has confirmed that combination therapy was not considered to be an important topic, as it was already naturally filtered into clinical practice indicating that there was no clinical uncertainty. Moreover, the recommendations in TA61 do not specify monotherapy. TA61 should not be appraised at this stage and can therefore be incorporated into the guideline. For TA176, there is new evidence from the COIN study that was ongoing at the time of TA176 which appears to indicates that cetuximab generally works less well than originally thought, with possibly some difference between different combinations of cetuxumab with chemotherapy. However, TA176 did not recommend cetuximab for the overall population, but only for the subgroup of patients who have metastases confined to the liver. The COIN study has not reported on this subgroup, so it would not affect the positive recommendation in TA176. However, the potential differences between different combination therapies in the

	overall population may need appraising at some later stage when the results of the further analyses are available. Therefore TA176 should not be re-appraised at this stage and cross-referenced in the guideline.

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:	TAs 61 and 176 should be incorporated and cross-referenced in the on-going clinical guideline respectively.

Respondent	**Response to proposal**	**Details**	**Comment from Technology Appraisals**
Association of Coloproctologists of Great Britain	Agree	I believe the recommendations are reasonable and fair, and do not have anything further to add at this stage.	Comment noted
Royal College of Nursing	Agree	They are not aware of any evidence likely to change the guidance.	Comment noted.
Medicines and Healthcare products Regulatory Agency	Agree	We are not aware of any new information that affects your proposals for dealing with these two guidances while constructing the clinical guideline on colorectal cancer.	Comment noted.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Royal College of Physicians / Royal College of Radiologists / National Cancer Research Institute / Association of Cancer Physicians / Joint Collegiate Council for Oncology	No objection	TA 61; Capecitabine and tegafur uracil for metastatic colorectal cancer - No additional information offered TA 176; Cetuximab for the first line treatment of metastatic colorectal cancer - Further evidence is now available from the COIN trial, from the relevant sub-group in terms of tumour response when cetuximab is given in combination with oxaliplatin and 5FU which supports the current NICE guidance. This has been presented at international meetings and is also in press with The Lancet.	Comment noted. It is noted that the new evidence from the COIN trial supports the current NICE Guidance and therefore does not have an impact on the current proposal.
Roche Products	Agree	We would agree that there is no new evidence with regards to capecitabine to inform a review of TA61 and that it is appropriate to incorporate this into the clinical guideline in development for colorectal cancer.	Comment noted.

No response received from:

Manufacturers/sponsors	General
• Merck Serono (tegafur uracil, cetuximab)	• Board of Community Health Councils in Wales

Patient/carer groups • Afiya Trust • Beating Bowel Cancer • Black Health Agency • Bladder and Bowel Foundation • Bowel Cancer UK • CANCERactive • Cancer Black Care • Cancer Equality • Chinese National Healthy Living Centre • Colostomy Association • Counsel and Care • Equalities National Council • Europacolon • Helen Rollason Heal Cancer Charity • IA: Ileostomy and Internal Pouch Support Group • Lynn's Bowel Cancer Campaign • Macmillan Cancer Support • Maggie's Centres • Marie Curie Cancer Care • Muslim Council of Britain • Muslim Health Network • Ostomy Lifestyle Centre • South Asian Health Foundation • Specialised Healthcare Alliance • Sue Ryder Care • Tenovus	• British National Formulary • Care Quality Commission • Commissioning Support Appraisals Service • Department of Health, Social Services and Public Safety for Northern Ireland • Healthcare Improvement Scotland • National Association of Primary Care • National Pharmacy Association • NHS Alliance • NHS Commercial Medicines Unit • NHS Confederation • Public Health Wales NHS Trust • Scottish Medicines Consortium Possible comparator manufacturer(s) • Actavis UK (irinotecan, oxaliplatin) • Goldshields Pharmaceuticals (calcium folinate) • Hospira UK (calcium folinate, fluorouracil, irinotecan, calcium levofolinate, oxaliplatin) • Medac UK (disodium folinate, fluorouracil, irinotecan, oxaliplatin) • Mylan UK (calcium folinate, irinotecan, oxaliplatin) • Pfizer (irinotecan, calcium folinate, calcium levofolinate) • Roche Diagnostics • Sanofi Aventis (oxaliplatin) • Teva UK (calcium folinate, irinotecan, oxaliplatin) • Winthrop (oxaliplatin) • Wockhardt UK (calcium folinate, fluorouracil, oxaliplatin)

Professional groups	Relevant research groups
• Association of Surgeons of Great Britain and Ireland • British Association for Services to the Elderly • British Association of Surgical Oncology • British Geriatrics Society • British Institute for Radiology • British Oncological Association (BOA) • British Psychosocial Oncology Society (BPOS) • British Society of Gastroenterology • Cancer Network Pharmacists Forum • Cancer Research UK • Pelican Cancer Foundation • Royal College of Anaesthetists • Royal College of General Practitioners • Royal College of Pathologists • Royal College of Surgeons • Royal Pharmaceutical Society • Royal Society of Medicine • Society and College of Radiographers • United Kingdom Clinical Pharmacy Association • United Kingdom Oncology Nursing Society Others • Department of Health • NHS Bolton • NHS Enfield • Welsh Assembly Government	• Bowel & Cancer Research • CORE (Digestive Disorders Foundation) • Institute of Cancer Research • MRC Clinical Trials Unit • National Cancer Research Network • National Institute for Health Research • Research Institute for the Care of Older People Assessment Group • Assessment Group tbc • National Institute for Health Research Health Technology Assessment Programme Associated Guideline Groups • National Collaborating Centre for Cancer Associated Public Health Groups • tbc

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