

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**GUIDANCE EXECUTIVE (GE)**

**Consideration of consultation responses on review proposal**

**Review of TA100; Colon cancer (adjuvant) - capecitabine and oxaliplatin**

This guidance was issued April 2006 with a review date of August 2012.

**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.

<b>Proposal put to consultees:</b>	The guidance should be incorporated into the on-going clinical guideline.
<b>Rationale for selecting this proposal</b>	Since TA100 was published, the licence for capecitabine has been extended to include combination therapy, in addition to the existing indication in TA100 of monotherapy. However, Topic Selection 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. There is no new evidence to suggest that an update of this appraisal is needed at this stage and we therefore recommend that this appraisal is incorporated into the guideline.

GE is asked to consider the original GE 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.

<b>Recommendation post consultation:</b>	The guidance should be incorporated into the on-going clinical guideline.
--	---

<b>Respondent</b>	<b>Response to proposal</b>	<b>Details</b>	<b>Comment from Technology Appraisals</b>
Association of Coloproctologists of Great Britain	Agree	I would agree with the recommendations and do not have anything further to add at this stage.	Comment noted.
Medicines and Healthcare products Regulatory Agency	No comment	We are not aware of any new information that affects your proposals for dealing with this guidance while constructing the clinical guideline on colorectal cancer.	Comment noted.
Royal College of Nursing	Agree	The approach that NICE is proposing seems appropriate. We are not aware of any evidence likely to change the guidance.	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	Disagree	<p>Capecitabine and oxaliplatin in the adjuvant treatment of stage III (Dukes' C) colon cancer is currently on the list of static guidance and therefore does not have a specified review date.</p> <p>This should be reviewed owing to the recent first results of the XELOXA trial which although immature for OS and comparative to now non standard regimens gives additional information with respect to DFS. This information is informative to NICE and clinicians and may have cost saving implications for the NHS and funders</p>	<p>Combination therapy (capecitabine + oxaliplatin) was considered as part of the Topic Selection process at NICE and was not considered to be a priority topic for NICE technology appraisal.</p> <p>The Topic Selection panel was aware that combination therapy has already naturally filtered into clinical practice indicating that there is no clinical uncertainty. It was concluded that developing new NICE guidance would not be a good use of NHS resources.</p>

**No response received from:**

<u>Manufacturers/sponsors</u>	<u>General</u>
<ul style="list-style-type: none"> <li>• Actavis UK (oxaliplatin)</li> <li>• Hospira UK (oxaliplatin)</li> <li>• Medac UK (oxaliplatin)</li> <li>• Mylan UK (oxaliplatin)</li> <li>• Roche Products (capecitabine)</li> <li>• Sanofi Aventis (oxaliplatin)</li> <li>• Teva UK (oxaliplatin)</li> <li>• Winthrop (oxaliplatin)</li> <li>• Wockhardt (oxaliplatin)</li> </ul>	<ul style="list-style-type: none"> <li>• Board of Community Health Councils in Wales</li> <li>• British National Formulary</li> <li>• Care Quality Commission</li> <li>• Commissioning Support Appraisals Service</li> <li>• Department of Health, Social Services and Public Safety for Northern Ireland</li> <li>• Healthcare Improvement Scotland</li> <li>• National Association of Primary Care</li> <li>• National Pharmacy Association</li> </ul>

### 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

- NHS Alliance
- NHS Commercial Medicines Unit
- NHS Confederation
- Public Health Wales NHS Trust
- Scottish Medicines Consortium

### Possible comparator manufacturer(s)

- Goldshields Pharmaceuticals (calcium folinate)
- Hospira UK (calcium folinate, fluorouracil, calcium levofolinate)
- Medac UK (disodium folinate, fluorouracil )
- Mylan UK (calcium folinate)
- Pfizer Ltd (calcium folinate, calcium levofolinate)
- Teva UK (calcium folinate)
- Wockhardt UK (calcium folinate, fluorouracil)

### Relevant research groups

- 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

### Professional groups

- Association of Cancer Physicians
- 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 Bedfordshire
- NHS City and Hackney
- Welsh Assembly Government

- National Institute for Health Research Health Technology Assessment Programme

### Associated Guideline Groups

- National Collaborating Centre for Cancer

### Associated Public Health Groups

- tbc

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

**Contributors to this paper:**

Technical Lead: Raisa Sidhu

Technical Adviser: Zoe Charles

Project Manager: Andrew Kenyon

13 June 2011