NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA 055 Guidance on the use of paclitaxel (first line only) in the treatment of ovarian cancer.

This guidance was issued in January 2003 and reviewed in December 2005. The decision was made to review the appraisal again on publication of the ICON5 trial results, which were published in March 2009.

Background

At the GE meeting on 4 August 2009 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	A review of the guidance should be transferred to the static guidance list.
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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	The guidance is transferred to the static guidance list.
post consultation:	

Respondent	Response to proposal	Details	Comment from Technology Appraisal
Bristol-Myers Squibb	Agree		Comment noted
British Gynaecological Cancer Society	Agree		Comment noted
Glaxo Smith Kline	Agree		Comment noted

National Collaborating Centre for Cancer and the Ovarian Cancer Guideline Development Group	Agree		Comment noted
National Public Health Service for Wales	Agree		Comment noted
Royal College of Nursing	Agree		Comment noted
Royal College of Pathologists	Agree		Comment noted
Royal College of Physicians, Medical Oncology Joint Special Committee	Disagree	The NCRI/RCP/RCR/ACP/JCCO is grateful to be asked to comment on this proposal. We feel the following points should be taken into consideration: 1. Review of paclitaxel should take account of ICON 7 and GOG 218. PFS data will be out 2010 but survival probably not until 2011-12. 2. The NICE review on initial guidelines of treatment of ovarian cancer is due 2011. It is important that at least the PFS data of the bevacizumab trials take account of this 3. There needs to be a view taken on the Japanese weekly study (for 1 and 2 above) which should be published by 2011 4. EORTC 55971 (neoadjuvant trial) should be available to 1 and 2	If the results of ICON 7 and GOG 218 (the bevacizumab trials) are likely to have a material effect on the current guidance then this topic can be transferred back to the active list and considered for review then. The ongoing guidelines will include recommendations about the treatment and management of stage 1 ovarian cancer. If the results of Japanese weekly study is likely to have a material effect on the current guidance then this topic can be transferred back to the active list and considered for review then. EORTC 55971 assesses the use of

above, and perhaps CHORUS too by then 5. The EORTC Erlotinib trial should be available by 2011 for 1 and 2 above.	carboplatin and cisplatin chemotherapy with and without debulking surgery. As paclitaxel is not assessed in this trial, it will not have an impact on the review of the guidance.
	EORTC Erlotinib assesses the use of erlotinib as maintainance therapy. As paclitaxel is not assessed in this trial, it will not have an impact on the review of the guidance.

No response received from:

Consultees	Consultees	Commentators (no right to submit or appeal)
Manufacturers/sponsors Actavis UK (paclitaxel) Hospira UK (paclitaxel) Pliva Pharma (paclitaxel) Teva UK (paclitaxel) Wockhardt UK (paclitaxel) Patient/carer groups Afiya Trust Age Concern and Help the Aged	Professional groups British Association for Services to the Elderly British Geriatrics Society British Oncological Association (BOA) British Psychosocial Oncology Society Cancer Networks Pharmacists Forum Cancer Research UK Children's Cancer and Leukaemia Group Royal College of General Practitioners	Possible comparator manufacturer(s) Actavis UK (gemcitabine) Eli Lilly and Company (gemcitabine) Hameln Pharmaceuticals (doxorubicin) Hospira UK (carboplatin, cisplatin, doxorubicin) Pfizer (cisplatin, doxorubicin) Pliva Pharma (carboplatin) Roche Products (bevacizumab) Schering-Plough (doxorubicin)
 Association for Children with Life Threatening or Terminal Conditions (ACT) Black Health Agency CANCERactive Cancer Black Care Cancer Equality Cancer Voices 	 Royal College of Obstetricians & Gynaecologists Royal College of Paediatrics and Child Health Royal Pharmaceutical Society Royal Society of Medicine – Intellectual Disabilities Forum United Kingdom Clinical Pharmacy Association United Kingdom Oncology Nursing Society 	 Sun Pharmaceuticals (gemcitabine) Teva UK (carboplatin, cisplatin, doxorubicin, gemcitabine) Wockhardt UK (carboplatin, cisplatin, doxorubicin) Relevant research groups

Consultees	Consultees	Commentators (no right to submit or appeal)
 Chinese National Healthy Living Centre CLIC Sargent Confederation of Indian Organisations Counsel and Care Equalities National Council Gynae C Helen Rollason Heal Cancer Charity Help Adolescents with Cancer Macmillan Cancer Support Maggie's Centres Marie Curie Cancer Care Muslim Council of Great Britain Muslim Health Network National Cancer Alliance National Council for Palliative Care Ovacome Ovarian Cancer Action South Asian Health Foundation Specialised Healthcare Alliance Sue Ryder Care Teenage Cancer Trust Tenovus Cancer Information Centre Well Being of Women Women's Health Concern 	Others Department of Health NHS Islington NHS West Kent Welsh Assembly Government Commentators (no right to submit or appeal) General Age Concern Cymru Board of Community Health Councils in Wales British National Formulary Cancer Care Cymru Department of Health, Social Services and Public Safety for Northern Ireland Medicines and Healthcare products Regulatory Agency National Association of Primary Care NHS Alliance NHS Confederation NHS Purchasing and Supplies Agency NHS Quality Improvement Scotland Scottish Medicines Consortium	 Eve appeal Institute of Cancer Research MRC Clinical Trials Unit National Cancer Research Network Policy Research Institute on Ageing and Ethnicity 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 Women's and Children's Health Associated Public Health Groups none

GE paper sign-off:

Nina Pinwill, Associate Director 23 September 2009

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