

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA101; Docetaxel for the treatment of hormone refractory prostate cancer

This guidance was issued June 2006 with a review date of April 2013 (following a previous review decision in August 2009).

Background

At the GE meeting of 21 February 2012 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' and incorporated into the on-going update of clinical guideline CG58 'Prostate cancer: diagnosis and management'.
Rationale for selecting this proposal	There is no new evidence that would be likely to affect the recommendations in TA101. Docetaxel is the standard of care for the treatment of metastatic hormone-refractory prostate cancer. Limited evidence from retrospective or observational studies suggests that docetaxel retreatment may be effective in a small number of highly selected patients and docetaxel is now available as a generic drug. This suggests that it may be beneficial to update recommendation 1.3 as part of the update of clinical guideline CG58 'Prostate cancer: diagnosis and management'. However, during the consultation on the scope the guideline update this was not identified as a priority.

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' and incorporated into the on-going update of clinical guideline CG58 'Prostate cancer: diagnosis and management'.
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Respondent	Response to proposal	Details	Comment from Technology Appraisals
MRC Clinical Trials Unit		I think there may be some other relevant trials which are not mentioned in Appendix B, although I have not yet looked at this in detail and accept that the names used for some of the trials presented might just be different to the names with which I am familiar.	Comment noted. Appendix B contains a summary of the ongoing and completed studies for docetaxel in this setting that were identified through clinical trials and publication databases and would therefore be expected to capture the most important information. No feedback was received from other consultees regarding any missing evidence. No change to the proposal is required.
Prostate Action	Agree	We would welcome the inclusion of this in the clinical guideline for prostate cancer.	Comment noted. No change to the proposal is required.
Healthcare Improvement Scotland	No comment	We have no comment to make on the proposal to incorporate the review of the above appraisal into a clinical guideline and have noted this in our records.	Comment noted. No change to the proposal is required.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
National Cancer Research Institute / Royal College of Physicians / Royal College of Radiologists / Association of Cancer Physicians	Agree	<p>Overall, our experts agree with the recommendation to transfer the guidance to the static list and incorporate it into the on-going update of clinical guideline CG58 – prostate cancer: diagnosis and management. We would also like to make the following comments.</p> <ul style="list-style-type: none"> • Our experts note that STAMPEDE is on the watchlist of trials. This is fine and appropriate. • If NICE are to include attention to the hormone-sensitive setting – something our experts support - then there are a series of other trials which should also be explicitly named in the proposal. • Our experts are unsure how the use of docetaxel in castration-resistant prostate cancer would be affected if the trials were to demonstrate that the drug was indicated earlier, in the hormone-naive setting. 	<p>Comments noted. NICE can only make recommendations in line with a drug’s UK marketing authorisation. Docetaxel’s marketing authorisation for prostate cancer presently covers only hormone-refractory metastatic stage (that is, remains unchanged from when the appraisal was originally conducted). There is therefore no need to take the hormone-sensitive setting into consideration for this review. Should a technology appraisal of docetaxel for the treatment of hormone-sensitive prostate cancer be proposed in the future, we would welcome any comments on relevant studies during consultation on the draft scope. No change to the proposal is required.</p>
National Collaborating Centre for Cancer		<p>We asked the Prostate Cancer Guideline Development Group for their views on this proposal. Although they agreed with the proposal to incorporate the update of docetaxel into the guideline, several members commented that the guideline would be more useful if it could cover all the drugs currently licensed for hormone refractory</p>	<p>Comment noted. As you have noted, several Single Technology Appraisals are ongoing for prostate cancer treatment which means these cannot be considered within the scope of the prostate cancer clinical guideline. No change to the proposal is required.</p>

Respondent	Response to proposal	Details	Comment from Technology Appraisals
		<p>prostate cancer.</p> <p>The NCC-C explained to the GDG members that we would not be able to look at any drugs that have already had a technology appraisal or where a technology appraisal is planned. As this applies to virtually all the drugs currently licensed for hormone refractory prostate cancer, except docetaxel, our review of this topic will be severely limited.</p>	
Royal College of Pathologists		<p>We believe that there is certainly no further evidence that we are aware of in relation to Docetaxel (“earlier review being beneficial”).</p> <p>In general Docetaxel works best for fit men (PS 0/1) who have metastatic CRPC and who either have or nearly have symptoms of disease progression. It is usually stopped after 8-10 cycles.</p>	Comments noted. No change to the proposal is required.
Royal College of Nursing	No comment	<p>Nurses caring for people with prostate cancer were invited to review the above technology appraisal.</p> <p>There are no further comments to make on this proposal on behalf of the Royal College of Nursing.</p>	Comment noted. No change to the proposal is required.

No response received from:

<p><u>Manufacturers/sponsors</u></p> <ul style="list-style-type: none">• Actavis UK (docetaxel)• Hospira UK(docetaxel)• Medac UK (docetaxel)• Sandoz (docetaxel)• Sanofi (docetaxel)• Teva UK (docetaxel) <p><u>Patient/carer groups</u></p> <ul style="list-style-type: none">• Afiya Trust• Black Health Agency• Bob Champion Cancer Trust• Cancer Black Care• Cancer Equality• Counsel and Care• Equalities National Council• Everyman• Helen Rollason Heal Cancer Charity• Macmillan Cancer Support• Maggie’s Centres• Marie Curie Cancer Care• Muslim Council of Great Britain• Muslim Health Network• Orchid• PCaSO – Prostate Cancer Network• Prostate Cancer Charity• Prostate Help Association• Prostate Cancer Support Federation• Specialised Healthcare Alliance	<p><u>General</u></p> <ul style="list-style-type: none">• Board of Community Health Councils in Wales• British National Formulary• Care Quality Commission• Commissioning Support Appraisals Service• Department of Health, Social Services and Public Safety for Northern Ireland• Medicines and Healthcare Products Regulatory Agency• National Association for Primary Care• National Pharmacy Association• NHS Alliance• NHS Commercial Medicines Unit• NHS Confederation• Public Health Wales NHS Trust• Scottish Medicines Consortium <p><u>Comparator manufacturers</u></p> <ul style="list-style-type: none">• Baxter Oncology (mitoxantrone)• Hospira UK (mitoxantrone)• Pfizer (mitoxantrone)• Sandoz (mitoxantrone)• Teva UK (mitoxantrone)• Wockhardt UK (mitoxantrone) <p><u>Relevant research groups</u></p> <ul style="list-style-type: none">• Cochrane Prostatic Diseases and Urologic Cancers Group• Institute of Cancer Research• National Cancer Research Network• National Institute of Health Research
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- South Asian Health Foundation
- Sue Ryder Care
- Tenovus

Professional groups

- British Association for Services to the Elderly
- British Association of Urological Nurses
- British Association of Urological Surgeons
- British Geriatrics Society
- British Institute of Radiology
- British Prostate Group
- British Psychosocial Oncology Society
- British Uro-Oncology Group BUG (added as requested by UCLH)
- Cancer Network Pharmacists Forum
- Cancer Research UK
- Pelican Cancer Foundation
- Royal College of General Practitioners
- Royal Society of Medicine
- Society and College of Radiographers
- United Kingdom Clinical Pharmacy Association
- United Kingdom Oncology Nursing Society

Others

- Bath and North East Somerset PCT
- Department of Health
- Pembrokeshire LHB
- Welsh Government

- Ovarian & Prostate Cancer Research Trust
- Pro-Cancer Research Foundation
- Research Institute of the Care of Older People

Assessment Group

- Assessment Group tbc
- National Institute for Health Research Health Technology Assessment Programme

Associated Public Health Groups

- None

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

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