

Docetaxel for hormone-refractory prostate cancer - summary of comments on draft scope from consultees

National Institute for Clinical Excellence

Section	Consultees	Comments	Action
Background information	Aventis	No comments	None
	Royal College of Physicians	The background information is accurate	None
The technology/ intervention	Aventis	Aventis have now gained market authorisation in the UK for hormone refractory metastatic prostate cancer in combination with prednisone or prednisolone.	Scope updated
Population	Aventis	Population – appropriate. No subgroups are able to be identified in the evidence base.	None
Comparators	Aventis	The published evidence shows that mitoxantrone is more effective than best supportive care.(Tannock 1997). No other palliative care agent has shown any survival benefit. Hence we believe that mitoxantrone is the only appropriate comparator for this technology.	Consultation with clinical experts indicated that estramustine may be used in some cases and that there may be variation in practice. This issue will be raised at the consultee meeting.

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	British Oncology Pharmacy Association	<p>It may be useful to also consider radiotherapy as a comparator as this is also a standard therapy.</p> <p>Docetaxel has been used in trials as both a three weekly and a weekly regimen with or without estramustine. The regimen or choice of regimens is likely to be identified in the marketing authorisation. However, the cost implications in terms of drugs and staff resources could be significantly different.</p>	<p>Scope amended to include a definition of active supportive care i.e. 'this may include radiotherapy, corticosteroids, oxygen, antibiotics and analgesics'</p> <p>Scope updated with information on the licensed dose/regimen. Docetaxel is licensed in combination with prednisone or prednisolone. The license states that it is administered as a 1-hour infusion every 3 weeks. This information will therefore be used in the cost-effectiveness analysis</p>
	Royal College of Physicians	Regarding standard comparators we would agree with those chosen. In addition there may be a trend for Docetaxel to be used earlier in the natural history of metastatic prostate cancer and therefore a further comparator that can be considered is second-line hormonal treatment.	As docetaxel is only licensed for hormone refractory prostate cancer, the appraisal can only cover this indication
	Royal College of Nurses	We agree with the scope and the list of standard comparators. They are well established.	None
Outcomes	Aventis	No comments	None
	Royal College of Nurses	As well as health-related quality of life, there is a need to look at pain response as one of the outcomes.	Pain included as an outcome

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	Royal College of Physicians	We agree with the outcome measures that have been selected. Other outcome measures that could be included are surrogate markers of effective palliation, e.g. the requirement for palliative radiotherapy, the requirement for bisphosphonates and analgesic requirement. (A reduction in the frequency of these palliative interventions could off-set the cost of Docetaxel in an economic analysis). This may be included additionally in the economic analysis section.	The outcome measures listed in the scope are not intended to be an exhaustive list, and consideration will be given to including these additional outcomes in the appraisal protocol
	The Prostate Cancer Charity	We are particularly concerned about outcomes data, in terms of adverse events and health related quality of life, and data on 'Other considerations' about the men for whom docetaxel is and perhaps isn't, an appropriate treatment. Thus we are pleased to see these mentioned. It may also be worth NICE considering and collating what other important research questions arise on its use as the data is gathered and sifted.	Research questions will be formulated as part of the usual NICE appraisal process
Economic analysis	Aventis	No comments	None
Other considerations	Aventis	No subgroups were identified in the tax 327 evidence base.	None
	Royal College of Physicians	We agree with the points raised in the "Other considerations" paragraph.	None
Additional comments on the draft scope.	Royal College of Nurses	It is recognised that there is a gap in treatment for prostate cancer so interventions that are less invasive but which can prolong quality of life of patients will be of a benefit. Given the two pivotal randomised controlled trials available, this may be a less complex evaluation.	None
	The Prostate Cancer Charity	In our opinion this covers the relevant areas we would expect to see.	None
	Royal College of Physicians	We believe the draft scope to be a sound document and agree with the appraisal objective.	None
	British Oncology Pharmacy Association	I could find no other comment on the scope. It appears to cover everything I would expect.	None

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The following consultees/commentators indicated that they had no comments on the draft scope

Baxter Healthcare Ltd, Board of Community Health Councils in Wales, British National Formulary, British Prostate Group, British Psychosocial Oncology Society, Greenwich Primary Care Trust, Department of Health, Marie Curie Cancer Care, Mayne Pharma Plc, MRC Clinical Trials Unit, Royal College of Pathologists, Royal College of Surgeons, Royal Pharmaceutical Society of Great Britain, Wyeth Pharmaceuticals, Welsh Assembly Government.