NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Technology Appraisals and Guidance Information Services

Static List Review (SLR)

Title and TA publication number of static topic:	TA101 Docetaxel for the treatment of hormone-refractory metastatic prostate cancer
Final decision:	The guidance will remain on the 'static guidance list'

1. Publication date:	June 2006
2. Date added to static list:	May 2012
3. Date the last searches were run:	January 2012
4. Current guidance:	1.1 Docetaxel is recommended, within its licensed indications, as a treatment option for men with hormone-refractory metastatic prostate cancer only if their Karnofsky performance-status score is 60% or more. 1.2 It is recommended that treatment with docetaxel should be stopped: • at the completion of planned treatment of up to 10 cycles, or • if severe adverse events occur, or

	• in the presence of progression of disease as evidenced by clinical or laboratory criteria, or by imaging studies. 1.3 Repeat cycles of treatment with docetaxel are not recommended if the disease recurs after completion of the planned course of chemotherapy.
5. Research recommendations from original guidance:	5.1 The Committee noted that there are ongoing trials, which include the MRC STAMPEDE study, and trials in which docetaxel plus prednisone or prednisolone is the standard treatment arm and is used in combination with other therapies such as zoledronic acid, strontium-89 and bevacizumab, in the experimental treatment arm. 5.2 The Committee identified a need for research to assess the quality of life associated with different treatments for hormone-refractory metastatic prostate cancer using generic quality of life instruments that are suitable for the purposes of cost-effectiveness analyses. The Committee also identified a need for research on the effects of docetaxel over a longer follow-up period, and in a patient group that is more representative of a wider patient population in terms of age, performance status and comorbidity, than in the RCTs considered in this appraisal.
6. Current cost of technology/ technologies:	Docetaxel (Taxotere, Sanofi-Aventis) 160mg/8ml = £1008.54 80mg/4ml = £504.25 20mg/1ml = £153.47 Source: BNF (May 2017)
7. Cost information from the TA (if available):	3.5 The net price of docetaxel (40 mg/ml) is £162.75 for a 0.5 ml vial and £534.75 for a 2 ml vial (excluding VAT; 'British national formulary', 50th edition). The cost per patient, assuming an average of seven cycles of treatment, would be approximately

	£8000. Costs may vary in different settings because of negotiated procurement discounts.
8. Alternative company(ies):	Accord Actavis Dr Reddy's Laboratory Hospira Medac UK
9. Changes to the original indication:	No change Current indication: TAXOTERE in combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostate cancer. Source: SPC (2015)
10. Ongoing trials cited in the 2012 RPP	Cabazitaxel Versus Docetaxel Both With Prednisone in Patients With Metastatic Castration Resistant Prostate Cancer (FIRSTANA trial) NCT01308567 – ongoing, completion expected October 2017 Prostate Cancer, Androgen Deprivation Withdrawal and Intermittent Chemotherapy (PON-PC-02 trial) NCT01224405 – completion date passed in 2016 but no updates posted Androgen Suppression Alone or Combined With Zoledronate, Docetaxel, Prednisolone, and/or Celecoxib in Treating Patients With Locally Advanced or Metastatic Prostate Cancer (STAMPEDE trial website) NCT00268476 – ongoing, completion expected 2020. Interim results include:

	James ND et al. (2009) Systemic therapy for advancing or metastatic prostate cancer (STAMPEDE): a multi-arm, multistage randomized controlled trial. *BJU Int*. 103(4): 464-9. James ND et al. (2012) Celecoxib plus hormone therapy versus hormone therapy alone for hormone-sensitive prostate cancer: first results from the STAMPEDE multiarm, multistage, randomised controlled trial. *Lancet Oncol*. 13(5): 549-58. James ND et al. (2016) Addition of docetaxel, zoledronic acid, or both to first-line long-term hormone therapy in prostate cancer (STAMPEDE): survival results from an adaptive, multiarm, multistage, platform randomised controlled trial. *Lancet*, 387(10024): 1163-77. James ND et al. (2016) Failure-Free Survival and Radiotherapy in Patients With Newly Diagnosed Nonmetastatic Prostate Cancer: Data From Patients in the Control Arm of the STAMPEDE Trial. *JAMA Oncol*. 2(3):348-57. Parker CC et al. (2013) Prostate radiotherapy for men with metastatic disease: a new comparison in the Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy (STAMPEDE) trial. *BJU Int*. 111(5): 697-9. Attard G et al. (2014) Combining enzalutamide with abiraterone, prednisone, and androgen deprivation therapy in the STAMPEDE trial. *Eur Urol*. 66(5): 799-802.
11. New relevant trials:	Study of Patient Preference Between Cabazitaxel and Docetaxel in First-line Chemotherapy for Metastatic Castrate-resistant Prostate Cancer NCT02044354

59 studies found for: (docetaxel OR taxceus OR taxotere) AND prostate | Phase 3, 4 | Studies updated from 01/01/2012 to 03/06/2018	
12. Relevant NICE guidance (published or in progress):	**Published** Prostate cancer (2016) NICE pathway Prostate cancer (2015) NICE quality standard 91 Prostate cancer: diagnosis and management (2014) NICE guideline CG175 Improving outcomes in urological cancers (2002) NICE guideline CSG2 Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases (2016) NICE technology appraisal guidance 412 Degarelix for treating advanced hormone-dependent prostate cancer (2016) NICE technology appraisal guidance 404 Cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel (2016) NICE technology appraisal guidance 391 Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated (2016) NICE technology appraisal guidance 387 Enzalutamide for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated (2016) NICE technology appraisal guidance 377 Enzalutamide for metastatic hormone-relapsed prostate cancer previously treated with a docetaxel-containing regimen (2014) NICE technology appraisal guidance 316

	Abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen (2012) NICE technology appraisal guidance 259 Hormone-sensitive metastatic prostate cancer: docetaxel (2016) NICE evidence summary ESUOM50 Prostate cancer: triptorelin (Decapeptyl SR) (2014) NICE evidence summary ESNM30 Prolaris gene expression assay for assessing long-term risk of prostate cancer progression (2016) Medtech innovation briefing 65 Irreversible electroporation for treating prostate cancer (2016) NICE interventional procedures guidance 572 Laparoscopic radical prostatectomy (2006) NICE interventional procedures guidance 193 Cryotherapy as a primary treatment for prostate cancer (2005) NICE interventional procedures guidance 145 Cryotherapy for recurrent prostate cancer (2005) NICE interventional procedures guidance 119 High-intensity focused ultrasound for prostate cancer (2005) NICE interventional procedures guidance 118 **In development** Prostate cancer NICE guideline. Publication expected May 2016

	Abiraterone for treating newly diagnosed metastatic hormone-naive prostate cancer NICE technology appraisal guidance [ID945]. Publication expected September 2018 **Proposed appraisals in Topic Selection** Apalutamide for treating non-metastatic hormone-relapsed prostate cancer before chemotherapy is indicated. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 8395 Apalutamide in combination with abiraterone acetate and prednisone for the treating prostate cancer. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 8835 Atezolizumab with enzalutamide for treating prostate cancer. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 9500 Custirsen for treating metastatic hormone relapsed prostate cancer. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 7214 Ipilimumab for treating chemotherapy naive, metastatic hormone-relapsed prostate cancer. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 7635 ODM-201 for treating high-risk, hormone-refractory, non-metastatic prostate cancer. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 9152

	Orteronel with prednisolone for treating metastatic hormone relapsed prostate cancer after docetaxel. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 6669 Orteronel for treating metastatic hormone-relapsed prostate cancer. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 7136. Pembrolizumab for treating prostate cancer. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 9411 Rilimogene galvacirepvec with rilimogene glafolivec for treating chemotherapy-naive metastatic hormone-relapsed prostate cancer. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 7033 Tasquinimod for treating metastatic hormone-relapsed prostate cancer after androgen deprivation therapy. Proposed NICE technology appraisal. Publication date to be confirmed. Topic selection number 7619
13. Relevant safety issues:	European Medicines Agency (10 March 2017) EMA reviewing cancer medicine docetaxel US Food and Drug Administration (20 June 2014) FDA Drug Safety Communication: FDA warns that cancer drug docetaxel may cause symptoms of alcohol intoxication after treatment

14. Any other additional relevant information or comments:	ESMO (2015) Cancer of the prostate: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up European Association of Urology (2015) Guidelines on prostate cancer NHS England (2016) Manual for prescribed specialised services 2016/17 Chapter 105 NHS England (2016) Clinical Commissioning Policy Statement: Docetaxel in combination with androgen deprivation therapy for the treatment of hormone naïve metastatic prostate cancer NHS England (July 2015) Clinical commissioning policy: Robotic-assisted surgical procedures for prostate cancer Policy reference: B14/P/a NHS England (June 2013) 2013/14 NHS standard contract for cancer: specialised kidney, bladder and prostate cancer services (adult) Service specification number: B14/S/a
15. Technical Lead comments and recommendation:	Docetaxel remains the standard of care for the treatment of metastatic hormone-refractory prostate cancer. There is no new evidence since the previous review that would be likely to affect the recommendations in TA101. Most evidence published since is from the STAMPEDE trial, in which docetaxel is given earlier in the course of the disease (in combination with hormone treatment). FIRSTANA appears to show that cabazitaxel is not inferior to docetaxel in the treatment of castration resistant prostate cancer not previously treated with chemotherapy. The same comparison is also being studied in an ongoing trial (NCT02044354), in this case using patient preference as its primary outcome. However, no updates are required to this recommendation based on this evidence. A

	separate appraisal of cabazitaxel would be required. Currently, the marketing authorisation is only for those previously treated with docetaxel. The PON-PC-02 trial aims to establish whether continuous or intermittent docetaxel regimens are superior. The status of the study is unknown and not verified since June 2010. Regardless, the results of this trial would not alter the recommendations in TA101.

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Appendix 1 – explanation of options

Options	Consequence	Selected – 'Yes/No'
The guidance will remain on the 'static guidance list'	The guidance will remain in place, in its current form, unless NICE becomes aware of substantive information which would make it reconsider. Searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	Yes
The decision to review the guidance will be deferred to specify date or trial	NICE will consider whether a review is necessary at the specified date. NICE will actively monitor the evidence available to ascertain when a consideration of a review is more suitable.	No
A full consideration of a review will be carried out through the Review Proposal Process	There is evidence that could warrant a review of the guidance. NICE will schedule a consideration of a review, including a consultation with relevant consultees and commentators.	No
The guidance will be withdrawn	The guidance is no longer relevant and an update of the existing recommendations would not add value to the NHS. NICE will schedule a consideration of a review, including a consultation with relevant consultees and commentators.	No

The guidance should be updated in an on-going clinical guideline.	Responsibility for the updating the technology appraisal passes to the NICE Clinical Guidelines programme. Once the guideline is published the technology appraisal will be withdrawn. NICE will schedule a consideration of a review, including a consultation with relevant consultees and commentators.	No