NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Review Proposal Project (RPP) decision paper

Review of TA259; Abiraterone for the treatment of metastatic, castrate-resistant prostate cancer following previous cytotoxic chemotherapy and TA316; Enzalutamide for the treatment of hormone refractory prostate cancer

Final recommendation post consultation
The guidance (both TA259 and TA316) should be incorporated into an on-going clinical guideline update. The technology appraisal guidance will remain extant alongside the guideline.

1. Background

This guidance was issued in July 2014

At the Guidance Executive meeting of 24 October 2017 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

2. Proposal put to consultees and commentators

The guidance should be incorporated into an on-going clinical guideline update. The technology appraisals will remain extant alongside the guideline. That we consult on this proposal.

3. Rationale for selecting this proposal

There is no new evidence which is likely to lead to a change in the recommendations in either of these guidance documents. Since these appraisals were carried out the treatment pathway for prostate cancer has changed and both abiraterone and enzalutamide can be used earlier in the treatment pathway. There is unlikely to be sufficient evidence for an appraisal of the cost effectiveness of sequential use of

these technologies after cytotoxic chemotherapy and the value of such an assessment may have changed since the time technology appraisal 316 was issued because people may now have already had either treatment before having cytotoxic chemotherapy.

The proposal is that the on-going review of Clinical Guideline 175 Prostate Cancer: Diagnosis and Management will include the recommendations of the technology appraisals. The technology appraisals will remain extant alongside the guideline. It will also be recommended that the technology appraisal guidance is moved to the static list until such time as the clinical guideline is considered for a further review.

This option has the effect of preserving the funding direction associated with a positive recommendation in these NICE technology appraisals.

4. Summary of consultee and commentator responses

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Respondent: Department of Health **Response to proposal:** No comment	**Comment from Technology Appraisals** Comment noted

Respondent: Janssen **Response to proposal:** Agree Janssen confirm that, to the best of our knowledge, there are no new data which could impact the NICE recommendation published for abiraterone acetate with presnisone/prednisolone in post-chemotherapy metastatic castrate-resistant prostate cancer (mCRPC) [TA259]. We acknowledge the LATITUDE and STAMPEDE trials have investigated the use of abiraterone acetate earlier in the prostate cancer pathway. Should NICE recommend the use of abiraterone acetate with prednisone/presnisolone in patients with newly diagnosed high risk metastatic hormone-sensitive prostate cancer (mHSPC) in combination with ADT [ID945], the decision to use it sequentially after cytotoxic chemotherapy in mCRPC could be affected. We welcome the opportunity to incorporate the TA259 into the on-going clinical guideline update.	**Comment from Technology Appraisals** Agreement noted Comment on the treatment pathway noted

Respondent: Prostate Cancer UK **Response to proposal:** Agree Prostate Cancer UK agree that TA259 and TA319 should be incorporated into the on-going Clinical Guideline 175 Prostate Cancer: Diagnosis and Management update. In the 'additional comments' section the proposal paper highlights the STAMPEDE and ARCHES trials and 'whether there are further points in the treatment pathway where abiraterone and enzalutamide are clinically effective is still being established.' The PEACE1 trial should also be considered and is looking at the combination of of ADT +/- Docetaxel +/- Local RT +/- Abiraterone Acetate in Metastatic Hormone-naïve Prostate Cancer. In addition, research has recently been published showing clinical benefit from the use of abiraterone in combination with ADT for men newly diagnosed with locally advanced and advanced metastatic prostate cancer. These results and the results from the LATITUDE trial should be incorporated alongside the upcoming NICE Technology Appraisal (ID945) decision, should abiraterone in combination with ADT be recommended for baseline commissioning. In addition, there is an increasing body of medical research that we would like the NICE to have on its radar. This includes: • Optimum use of cabazitaxel showing that a lower dose delivered equal overall survival and reduced toxicity • Evidence on Focal Therapies • Ga-PSMA PET/CT impact on prostate cancer management There also needs to be a place holder for sequential biopsy of men with metastatic disease either through bone biopsies or liquid biopsies looking at CTCs or cfDNA.	**Comment from Technology Appraisals** Agreement noted Thank you for your comments on current research on treatments for prostate cancer and biomarkers, which are noted. NICE welcomes the continued engagement of Prostate Cancer UK on ongoing and future appraisals of technologies for treating prostate cancer.

Paper signed off by: Jenniffer Prescott, 18 December 2017

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