

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Enzalutamide for treating non-metastatic hormone-relapsed prostate cancer

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of enzalutamide within its marketing authorisation for treating non-metastatic hormone-relapsed prostate cancer.

Background

Prostate cancer is a condition in which tumours develop in the prostate, a gland in the male reproductive system. The exact cause is unknown but environmental and genetic factors are associated with an increased risk of developing prostate cancer.^{1,2}

The incidence of prostate cancer increases with age and is higher in people of black African-Caribbean family origin and people with a family history of the condition.¹ In England in 2016, about 40,500 people were diagnosed with prostate cancer³ and about 9,900 people died from the condition.⁴ Between 2015 to 2016, 84% of people diagnosed in England with prostate cancer had non-metastatic disease, that is, disease that has not spread to other parts of the body (for example, the bones).⁵ Non-metastatic disease includes localised prostate cancer, where the cancer is confined to the prostate, and locally advanced prostate cancer, where the cancer has spread to the area just outside the prostate.

NICE clinical guideline 175 classifies localised prostate cancer to be at low, intermediate or high risk of progression based on prostate-specific antigen concentration, Gleason score (based on a biopsy) and clinical stage. People with intermediate or high risk non-metastatic prostate cancer may be offered hormone therapy. Prostate cancer may initially respond to hormone therapy but eventually become resistant to it. This clinical condition is described as 'hormone-relapsed' prostate cancer, but the terms 'castration-resistant prostate cancer', 'hormone-refractory prostate cancer' and 'androgen-independent prostate cancer' are also used.^a Hormone-relapsed prostate cancer is diagnosed by rising prostate-specific antigen levels.

^aIn January 2013, NICE and the Department of Health and Social Care agreed that, following feedback received from stakeholders during scoping and appraisal consultations, the term 'castration resistant prostate cancer' should be replaced with 'hormone relapsed prostate cancer'. This has been implemented for all appraisals from January 2013.

There are currently no licensed treatments for non-metastatic, hormone-relapsed prostate cancer. The main treatment is androgen deprivation therapy which may include anti-androgens, such as, bicalutamide. Everyone is monitored for evidence of disease metastasis, at which point, other treatments are considered.

The technology

Enzalutamide (Xtandi, Astellas Pharma) is an androgen receptor antagonist that acts on different steps in the androgen receptor signalling pathway to decrease proliferation of cancer cells and induce cancer cell death leading to tumour regression. Enzalutamide is administered orally.

Enzalutamide does not currently have a marketing authorisation in the UK for the treatment of non-metastatic prostate cancer. Enzalutamide plus androgen deprivation therapy is being studied in a clinical trial, compared with placebo plus androgen deprivation therapy, in adults with non-metastatic hormone-relapsed prostate cancer.

Enzalutamide has a marketing authorisation in the UK for the treatment of metastatic hormone-relapsed prostate cancer in adults after failure of androgen deprivation therapy, and following progression after docetaxel therapy.

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| Intervention(s) | Enzalutamide with androgen deprivation therapy |
| Population(s) | Adults with non-metastatic hormone-relapsed prostate cancer |
| Comparators | Androgen deprivation therapy |
| Outcomes | <p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • Metastasis-free survival • Time to prostate-specific antigen progression • Overall survival • Adverse effects of treatment • Health-related quality of life. |

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| Economic analysis | <p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any patient access schemes for the intervention or comparator technologies will be taken into account.</p> |
| Other considerations | <p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p> |
| Related NICE recommendations and NICE Pathways | <p>Related Interventional Procedures</p> <p>‘Laparoscopic radical prostatectomy’ (2006) NICE interventional procedures guidance 193.</p> <p>‘High dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer’ (2006) NICE interventional procedures guidance 174.</p> <p>‘Cryotherapy as a primary treatment for prostate cancer’ (2005) NICE interventional procedures guidance 145.</p> <p>‘Low dose rate brachytherapy for localised prostate cancer’ (2005) NICE interventional procedures guidance 132.</p> <p>‘Cryotherapy for recurrent prostate cancer’ (2005) NICE interventional procedures guidance 119.</p> <p>‘High-intensity focused ultrasound for prostate cancer’ (2005) NICE interventional procedures guidance 118.</p> <p>Related Guidelines</p> <p>‘Prostate cancer: diagnosis and management’ (2014) NICE guideline 175. Review date to be confirmed.</p> <p>Related Quality Standards</p> <p>‘Prostate cancer’ (2015) NICE quality standard 91.</p> |

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| | <p>Related NICE Pathways</p> <p>‘Prostate cancer’ (2018) NICE Pathway.</p> |
| Related National Policy | <p>NHS England (2017) Manual for Prescribed Specialised Services 2017/18. Specialist cancer services (adults): section 105.</p> <p>Department of Health (2016) NHS Outcomes Framework 2016-2017: Domains 1-2.</p> |

References

1. Cancer Research UK (2015) [Prostate cancer risks and causes](#). Accessed July 2018.
2. Macmillan Cancer Support (2015) [Potential causes of prostate cancer](#). Accessed July 2018.
3. Office for National Statistics (2018) [Cancer registration statistics, England, 2016](#). Accessed July 2018.
4. Cancer Research UK (2018) [Prostate cancer mortality statistics](#). Accessed July 2018.
5. National Prostate Cancer Audit (2017) [Annual report 2017](#). Accessed July 2018.