NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Abiraterone (originator and generics) for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer (review of TA721) [ID6378]

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of abiraterone within its marketing authorisation for treating newly diagnosed high risk metastatic hormone-naive prostate cancer.

Background

Prostate cancer is a condition in which tumours develop in the prostate, a gland in the male reproductive system.[1] The exact cause is unknown but environmental and genetic factors are associated with an increased risk of developing prostate cancer.[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.[2] 54,628 people were diagnosed with prostate cancer in England during 2023[3]. Between 2020 to 2021, 19% of people diagnosed in England had metastatic disease, that is, disease that has spread to other parts of the body (for example, the bones).[4]

NICE guideline (NG)131 recommends androgen deprivation therapy (luteinising hormone-releasing hormone agonist therapy, bicalutamide monotherapy or bilateral orchidectomy) for people whose prostate cancer is sensitive to such hormonal therapy. For metastatic (or advanced) hormone sensitive prostate cancer, NICE technology appraisal guidance (TA)995 recommends relugolix as an alternative androgen deprivation therapy. Docetaxel can also be added within 12 weeks of starting androgen deprivation therapy. Newer hormonal treatments, enzalutamide, apalutamide and darolutamide (with docetaxel) are also recommended as treatment options with androgen deprivation therapy in people with metastatic prostate cancer (NICE TA712, 741 and 903 respectively). However, apalutamide is only recommended if docetaxel is not suitable. Abiraterone (originator) with prednisone or prednisolone and androgen deprivation therapy is not recommended for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer (NICE TA721).

The technology

Abiraterone (Zytiga, Janssen) has a UK marketing authorisation for treating newly diagnosed high risk metastatic hormone sensitive prostate cancer in adults in combination with androgen deprivation therapy.

Intervention(s)	Abiraterone with prednisolone and androgen deprivation therapy

© National Institute for Health and Care Excellence 2024. All rights reserved.

Population(s)	Adults with newly diagnosed high risk metastatic hormone-naive prostate cancer
Comparators	Traditional standard of care treatments: • androgen deprivation therapy alone (including orchidectomy, luteinising hormone-releasing hormone agonist therapy or monotherapy with bicalutamide) • relugolix • docetaxel with androgen deprivation therapy Novel hormonal agents: • enzalutamide with androgen deprivation therapy • apalutamide with androgen deprivation therapy • darolutamide with docetaxel and androgen deprivation therapy • darolutamide with androgen deprivation therapy (subject to NICE evaluation)
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rate • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out. 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. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products should be taken into account.

© National Institute for Health and Care Excellence 2024. All rights reserved.

Other considerations	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.
Related NICE recommendations	**Related technology appraisals:** Relugolix for treating hormone-sensitive prostate cancer (2024). NICE Technology appraisal guidance [TA995] Darolutamide with androgen deprivation therapy and docetaxel for treating hormone-sensitive metastatic prostate cancer (2023). NICE Technology appraisal guidance [TA903] Apalutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer (2021). NICE Technology appraisal guidance [TA741]. Review date 2024. Abiraterone for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer (2021). NICE Technology appraisal guidance [TA721]. Review date 2024. Enzalutamide for treating hormone-sensitive metastatic prostate cancer (2021). NICE Technology appraisal guidance [TA712]. **Related technology appraisals in development:** Darolutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer. NICE Technology appraisal guidance [TSID 12045]. Niraparib with abiraterone acetate and prednisone for treating hormone-sensitive metastatic prostate cancer. NICE Technology appraisal guidance [TSID 12044]. **Related NICE guidelines:** Prostate cancer: diagnosis and management (2019). NICE guideline [NG131]. **Related quality standards:** Prostate cancer (2015). NICE quality standard [QS91].
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan. NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Specialist cancer services (adults) [section 105]. Department of Health (2016) Department of Health and Social Care, NHS Outcomes Framework 2016-2017 Domains 1-5. NHS England (2013) NHS England B14/S/a 2013/14 NHS standard contract for cancer: specialised kidney, bladder and prostate cancer services (adult).

© National Institute for Health and Care Excellence 2024. All rights reserved.

	NHS England (2016) Clinical Commissioning Policy Statement: Docetaxel in combination with androgen deprivation therapy for the treatment of hormone naïve metastatic prostate cancer

Questions for consultation

Where do you consider abiraterone will fit into the existing care pathway for newly diagnosed high risk metastatic hormone-naive prostate cancer?

What factors influence treatment decisions in this population?

Please select from the following, will abiraterone be:

A. Prescribed in primary care with routine follow-up in primary care

B. Prescribed in secondary care with routine follow-up in primary care

C. Prescribed in secondary care with routine follow-up in secondary care

D. Other (please give details):

For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

NICE is considering evaluating this technology through its cost comparison evaluation process.

Please provide comments on the appropriateness of appraising this topic through this process.

(Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

Technologies can be evaluated through the cost-comparison process if they are expected to provide similar or greater health benefits, at a similar or lower cost, compared with technologies that have been previously recommended (as an option) in published NICE guidance for the same indication. Companies can propose cost-comparison topics to NICE at any stage during topic selection and scoping. NICE will route technologies for evaluation through the cost-comparison process if it is agreed during scoping that the process is an appropriate route to establish the clinical and cost effectiveness of the technology.

NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made.

- Which of the listed novel hormonal agents are used most frequently in people with newly diagnosed high risk metastatic hormone-naive prostate cancer? Are any used in particular subgroups?
- Is the technology likely to be similar in its clinical effectiveness, safety and resource use to any of the comparators? Or in what way is it different to the comparators?

© National Institute for Health and Care Excellence 2024. All rights reserved.

- Will the intervention be used in the same place in the treatment pathway as the comparator(s)?
- Have there been any major changes to the treatment pathway recently? If so, please describe.
- Will the intervention be used to treat the same population or subgroups as the comparator(s)?
- Overall is the technology likely to offer similar or improved health benefits compared with all of the comparators listed in the scope?
- Would it be appropriate to use the cost-comparison methodology for this topic?

Do you consider that the use of abiraterone can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which abiraterone is licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

References

1. Cancer Research UK (2019) What is prostate cancer? Accessed July 2023.
2. Macmillan Cancer Support (2021) Potential causes of prostate cancer. Accessed July 2023.
3. National Prostate Cancer Audit (2024) NPCA Quarterly Report January 2021 to December 2023
4. National Prostate Cancer Audit (2024) State of the Nation Report Infographic.

© National Institute for Health and Care Excellence 2024. All rights reserved.