

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Darolutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer ID6452

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of darolutamide with androgen deprivation therapy within its marketing authorisation for treating hormone-sensitive metastatic 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 mainly affects people over 50, with the risk increasing with age, and is higher in people of black African-Caribbean family origin or people with a family history of the condition.¹ In 2022, 50,702 people in England were diagnosed with prostate cancer.³ Of those, 19% of people diagnosed had metastatic disease, that is, disease that has spread to other parts of the body (for example, the bones).³ The prostate cancer incidence rates are projected to increase by 15% between 2023-2025 in the UK.¹ The age standardised mortality rate for prostate cancer in 2021 was 43 for every 100,000 persons.⁴

For newly diagnosed metastatic prostate cancer, [NICE clinical guideline 131](#) recommends starting docetaxel chemotherapy within 12 weeks of starting androgen deprivation therapy. For metastatic prostate cancer, the guideline recommends offering bilateral orchidectomy as an alternative to continuous luteinising hormone-releasing hormone agonist therapy. For people who are willing to accept the adverse impact on overall survival and gynaecomastia (breast swelling) in the hope of retaining sexual function, the guideline recommends offering anti-androgen monotherapy with bicalutamide. [NICE technology appraisal 404](#) recommends degarelix, a gonadotrophin-releasing hormone antagonist, for treating advanced hormone-dependent (hormone-sensitive) prostate cancer in people with spinal metastases. In addition, [NICE technology appraisal 712](#) recommends enzalutamide plus androgen deprivation therapy as an option for treating hormone-sensitive metastatic prostate cancer in adults, and [NICE technology appraisal 741](#) recommends apalutamide plus androgen deprivation therapy as an option for treating hormone-sensitive metastatic prostate cancer in adults, if docetaxel is not suitable. [NICE technology appraisal 903](#) recommends darolutamide with androgen deprivation therapy and docetaxel as another option for treatment of hormone-sensitive metastatic prostate cancer in adults. [NICE technology appraisal 995](#) recommends relugolix as another option for treating prostate cancer in adults with advanced hormone-sensitive prostate cancer.

The description 'hormone-sensitive metastatic prostate cancer' refers to a population that includes people with metastatic prostate cancer who have not had androgen

deprivation therapy, or whose disease is continuing to respond to androgen deprivation therapy.

The technology

Darolutamide (Nubeqa, Bayer) does not currently have a marketing authorisation in the UK for treating hormone-sensitive metastatic prostate cancer. Darolutamide does have a marketing authorisation in the UK for treating non-metastatic castration resistant prostate cancer -in adults at high risk of developing metastatic disease and for treating hormone-sensitive metastatic prostate cancer in combination with docetaxel.

Intervention(s)	Darolutamide with androgen deprivation therapy
Population(s)	People with hormone-sensitive metastatic prostate cancer
Subgroups	<p>If the evidence allows, the following subgroups of people will be considered:</p> <ul style="list-style-type: none"> • people with newly diagnosed metastatic prostate cancer • people with high-risk metastatic prostate cancer
Comparators	<ul style="list-style-type: none"> • Androgen deprivation therapy alone (including orchidectomy, luteinising hormone-releasing hormone agonist therapy, degarelix, relugolix, monotherapy with bicalutamide) • Docetaxel and androgen deprivation therapy • Darolutamide with androgen deprivation therapy and docetaxel • Enzalutamide and androgen deprivation therapy • Apalutamide with androgen deprivation therapy
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • overall survival • progression-free survival • response rate • prostate-specific antigen response • time to prostate-specific antigen progression • adverse effects of treatment • health-related quality of life.

<p>Economic analysis</p>	<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>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.</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 commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
<p>Other considerations</p>	<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>
<p>Related NICE recommendations</p>	<p>Related technology appraisals:</p> <p>‘Relugolix for treating hormone-sensitive prostate cancer’ (2024). NICE Technology appraisal guidance [TA995].</p> <p>‘Darolutamide with androgen deprivation therapy and docetaxel for treating hormone-sensitive metastatic prostate cancer’ (2023). NICE Technology appraisal guidance [TA903]. Review date 2026.</p> <p>‘Apalutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer’ (2021). NICE Technology appraisal guidance [TA741]. Review date 2024.</p> <p>‘Enzalutamide for treating hormone-sensitive metastatic prostate cancer’ (2021). NICE Technology appraisal guidance [TA712]. Review date 2024.</p> <p>‘Darolutamide with androgen deprivation therapy for treating hormone-relapsed non-metastatic prostate cancer’ (2020). NICE Technology appraisal guidance [TA660]. Review date 2023.</p> <p>‘Degarelix for treating advanced hormone-dependent prostate cancer’ (2016). NICE Technology appraisal guidance [TA404].</p>

	<p>Related NICE guidelines:</p> <p>‘Prostate cancer: diagnosis and management’ (2019). NICE guideline [NG131].</p> <p>Related Quality Standards:</p> <p>‘Prostate cancer’ (2015). NICE quality standard [QS91].</p>
<p>Related National Policy</p>	<p>The NHS Long Term Plan (2019) NHS Long Term Plan</p> <p>NHS England (2023) Manual for prescribed specialist services (2023/2024)</p> <p>NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019)</p> <p>NHS England (2021) Clinical Commissioning Policy: External beam radiotherapy for patients presenting with hormone sensitive, low volume metastatic prostate cancer at the time of diagnosis</p> <p>NHS England (2016) Clinical Commissioning Policy Statement: Docetaxel in combination with androgen deprivation therapy for the treatment of hormone naïve metastatic prostate cancer</p> <p>NHS England (2013) 2013/14 NHS standard contract for cancer: chemotherapy (adult)</p>

Questions for consultation

Where do you consider darolutamide with androgen deprivation therapy will fit into the existing care pathway for hormone-sensitive metastatic prostate cancer?

Please select from the following, will darolutamide with androgen deprivation therapy 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.

Would darolutamide with androgen deprivation therapy be a candidate for managed access?

Do you consider that the use of darolutamide with androgen deprivation therapy 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 darolutamide with androgen deprivation therapy 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.

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.

- Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators?
- 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 as the comparator(s)?
- Overall is the technology likely to offer similar or improved health benefits compared with the comparators?

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- Would it be appropriate to use the cost-comparison methodology for this topic?

References

1. Cancer Research UK (2024). [Prostate cancer statistics](#). Accessed October 2024.
2. Macmillan Cancer Support (2021). [Causes and risk factors of prostate cancer](#). Accessed October 2024.
3. National Prostate Cancer Audit (2024). [NPCA State of the Nation Report 2023](#). Accessed October 2024.
4. NHS Digital (2024). [Cancer registration statistics, England 2021](#). Accessed October 2024.