NICE National Institute for Health and Care Excellence

NICE guidance

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

Technology appraisal guidance
Published: 12 November 2025

www.nice.org.uk/guidance/ta1109

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 Darolutamide with androgen deprivation therapy (ADT) can be used as an option to treat hormone-sensitive metastatic prostate cancer in adults, only if:

- docetaxel is not suitable
- the company provides darolutamide according to the commercial arrangement.

1.2 Use the least expensive option of the suitable treatments (including darolutamide with ADT and apalutamide with ADT), having discussed the advantages and disadvantages of the available treatments with the person with the condition. Take account of administration costs, dosages, price per dose and commercial arrangements.

1.3 These recommendations are not intended to affect treatment with darolutamide with ADT that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop.

What this means in practice

Darolutamide with ADT must be funded in the NHS in England for the condition and population in the recommendations, if it is considered the most suitable treatment option. Darolutamide with ADT must be funded in England within 30 days of final publication of this guidance.

There is enough evidence to show that darolutamide with ADT provides benefits and value for money, so it can be used routinely across the NHS in this population.

NICE has produced tools and resources to support the implementation of this guidance.

Why these recommendations were made

Usual treatment for hormone-sensitive metastatic prostate cancer usually includes ADT. ADT may be given alone, or with enzalutamide, apalutamide, docetaxel, or darolutamide plus docetaxel. Darolutamide plus ADT works in a similar way to enzalutamide plus ADT and apalutamide plus ADT. It would be offered to the same population as apalutamide plus ADT, that is, people who cannot have docetaxel.

Clinical trial evidence shows that darolutamide plus ADT is more effective than placebo. Darolutamide plus ADT has not been directly compared in a clinical trial with apalutamide plus ADT. But indirect comparisons suggest that it is likely to be as effective.

A cost comparison suggests that the costs for darolutamide plus ADT are similar to or lower than those for apalutamide plus ADT. To be recommended as a treatment option, darolutamide plus ADT has to cost less or have similar costs to 1 relevant comparator recommended in a published technology appraisal guidance (see NICE's cost-comparison methods). So, darolutamide plus ADT can be used.

For all evidence, see the committee papers. For more information on NICE's evaluation of apalutamide plus ADT, see the committee discussion section in NICE's technology appraisal guidance on apalutamide with ADT for treating hormone-sensitive metastatic prostate cancer.

2 Information about darolutamide

Marketing authorisation indication

2.1 Darolutamide (Nubeqa, Bayer) is indicated for 'the treatment of adult men with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for darolutamide.

Price

2.3 The list price of darolutamide is £4,040.00 for a 28-day supply of 112 x 300 mg tablets (excluding VAT, BNF online accessed September 2025).

2.4 The company has a commercial arrangement. This makes darolutamide available to the NHS with a discount. The size of the discount is commercial in confidence.

Carbon Reduction Plan

2.5 For information, the Carbon Reduction Plan for UK carbon emissions is published on Bayer's Climate Commitment: Net Zero by 2050 webpage.

3 Implementation

3.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 90 days of its date of publication. Because darolutamide with androgen deprivation therapy has been recommended through the cost-comparison process, NHS England and integrated care boards have agreed to provide funding to implement this guidance 30 days after publication.

3.2 Chapter 2 of Appraisal and funding of cancer drugs from July 2016 (including the new Cancer Drugs Fund) – A new deal for patients, taxpayers and industry states that for those drugs with a draft recommendation for routine commissioning, interim funding will be available (from the overall Cancer Drugs Fund budget) from the point of marketing authorisation, or from release of positive draft guidance, whichever is later. Interim funding will end 90 days after positive final guidance is published (or 30 days in the case of drugs with an Early Access to Medicines Scheme designation or cost comparison evaluation), at which point funding will switch to routine commissioning budgets. The NHS England Cancer Drugs Fund list provides up-to-date information on all cancer treatments recommended by NICE since 2016. This includes whether they have received a marketing authorisation and been launched in the UK.

3.3 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 60 days of the first publication of the final draft guidance.

3.4 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has hormone-sensitive metastatic prostate cancer and the healthcare professional responsible for their care thinks that darolutamide with androgen deprivation therapy is the right treatment, it should be available for use, in line

with NICE's recommendations.

4 Evaluation committee members

The highly specialised technologies evaluation committee is a standing advisory committee of NICE. This topic was considered as a cost comparison evaluation by the lead team of the HST committee, which includes the chair and vice chair.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

Chair

Paul Arundel and Iolo Doull
Chair, highly specialised technologies evaluation committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Emma McCarthy
Technical lead

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Technical adviser

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Project manager

Richard Diaz
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