

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

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

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 (see [section 2](#)).
- 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.

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 Information on the Carbon Reduction Plan for UK carbon emissions for Bayer will be included here when guidance is published.

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.

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.

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