NICE National Institute for Health and Care Excellence

NICE guidance

Abiraterone (originator and generics) for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer

Technology appraisal guidance
Published: 19 November 2025

www.nice.org.uk/guidance/ta1110

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

This guidance replaces TA721.

1 Recommendations

1.1 Abiraterone plus androgen deprivation therapy (ADT), with prednisolone or prednisone can be used, within its marketing authorisation, as an option to treat newly diagnosed high-risk hormone-sensitive metastatic prostate cancer in adults.

What this means in practice

Abiraterone plus ADT, with prednisolone or prednisone must be funded in the NHS in England for the condition and population in the recommendation, if it is considered the most suitable treatment option. Abiraterone plus ADT, with prednisolone or prednisone must be funded in England within 30 days of final publication of this guidance.

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

Prednisone is not currently available in England, but it is included in the recommendation to match the abiraterone marketing authorisation.

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

Why this recommendation was made

This evaluation is a review of NICE technology appraisal guidance TA721.

Usual treatment for newly diagnosed high-risk hormone-sensitive metastatic prostate cancer is enzalutamide plus ADT or apalutamide plus ADT. Abiraterone plus ADT, with prednisolone or prednisone works in a similar way to these treatments, and would be

offered to the same population.

Clinical trial evidence shows that abiraterone plus ADT, with prednisolone or prednisone is more effective than placebo plus ADT and ADT alone. Abiraterone plus ADT, with prednisolone or prednisone has not been directly compared in a clinical trial with enzalutamide plus ADT or apalutamide plus ADT, but indirect comparisons suggest that it is likely to work as well as these combinations.

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

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

Marketing authorisation indication

2.1 Abiraterone (generic) is indicated 'with prednisone or prednisolone for the treatment of newly diagnosed high risk metastatic hormone sensitive prostate cancer (mHSPC) in adult men in combination with androgen deprivation therapy (ADT)'.

Dosage in the marketing authorisation

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

Price

2.3 The list price of abiraterone varies by pack size or dose (BNF online, accessed September 2025).

2.4 Costs may vary in different settings because of negotiated procurement discounts.

Carbon Reduction Plan

2.5 For information, a Carbon Reduction Plan for UK carbon emissions is not included because there are multiple companies that manufacture abiraterone.

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 abiraterone plus androgen deprivation therapy (ADT), with prednisolone or prednisone 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 newly diagnosed high-risk hormone-sensitive metastatic prostate cancer and the healthcare professional responsible for their care thinks that abiraterone plus ADT, with prednisolone or prednisone is the right treatment, it

should be available for use, in line with NICE's recommendations.

4 Evaluation committee members and NICE project team

Evaluation committee members

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

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
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.

Giacomo De Guisa
Technical lead

Albany Chandler
Technical adviser

Thomas Feist
Project manager

Richard Diaz

Associate director

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