Publication date: 19 December 2025

Clinical commissioning policy:

Abiraterone acetate and prednisolone for high-risk, hormone sensitive, non-metastatic prostate cancer (adults) [2312]

Summary

Abiraterone acetate and prednisolone are recommended to be available as a routine commissioning treatment option for high-risk, hormone sensitive, non-metastatic prostate cancer (newly diagnosed high-risk or relapsing with high-risk features) within the criteria set out in this document. The use of abiraterone acetate in this indication is off-label.

The policy is restricted to adults as this reflects the population affected by prostate cancer.

Committee discussion

Clinical Panel considered the evidence base and the policy proposition and recommended this proceed as a routine commissioning policy. Please see Clinical Panel reports for full details of Clinical Panel's discussion.

The Clinical Priorities Advisory Group committee papers can be accessed on the NHS England website.

What we have decided

NHS England has carefully reviewed the evidence to treat hormone sensitive, non-metastatic prostate cancer (newly diagnosed high-risk or relapsing with high-risk features) with abiraterone acetate and prednisolone. We have concluded that there is enough evidence to make the treatment available at this time.

The evidence review which informs this commissioning position can be accessed the NHS England website.

Links and updates to other policies

Please refer to Appendix A for all related policies, guidance and specifications.

Plain language summary

About prostate cancer

Prostate cancer is the most common cancer in men[1], and the second most common cancer in the UK. About 1 in 8 men will get prostate cancer at some point in their life. Men who are older, with a family history of prostate cancer and of Afro-Caribbean origin are more at risk of developing the disease (NICE, 2021).

When prostate cancer is diagnosed it is 'staged and graded'. Grading is based upon International Society of Urological Pathology (ISUP) grade groups 1-5 and predicts how aggressively the tumour will behave. Staging provides an indication of how large the cancer is as well as how far it has spread. Localised prostate cancer is when the cancer is contained within the prostate and has not spread anywhere else in the body but could include spread to local pelvic lymph nodes.

Tumour Node Metastasis (TNM) staging system:

- T – describes the size and extent of the tumour from 1 (impalpable) to 4 (involving adjacent structures)
- N – describes the presence of involved lymph nodes from 0 (none) to 1 (present)
- M – describes whether the cancer has metastasised from 0 (non-metastatic) to 1 (metastatic)

Prostate cancer can also be assessed and risk stratified with a Gleason score (a pathology grade from six to 10 based on how quickly the prostate cells are likely to grow or how aggressive the cells look) and the blood level of prostate specific antigen (PSA) (a protein produced by prostate cells).

Newly diagnosed high-risk prostate cancer

High risk[2], non-metastatic prostate cancer would be classified as:

- Non-metastatic (M0)

AND EITHER

- node positive (N1)

OR

- node negative (N0) with at least two of:
  - tumour stage T3 or T4
  - Gleason score 8-10
  - Prostate specific antigen (PSA) ≥ 40nanograms/ml

Relapsing with high-risk features prostate cancer

Patients with previously treated prostate cancer with radical surgery or radiotherapy that is relapsing with high-risk features would also be considered as part of this cohort.

Relapsed prostate cancer with high-risk features would be classified as previously radically treated prostate cancer with an interval of ≥12 months without treatment and:

[1] In this policy the term 'men' is used, based on the source evidence used in its development. This policy is also relevant to people with male anatomy who do not identify as men.
[2] High-risk primary prostate cancer can also be defined by Cambridge Prognostic Group (CPG) 4 or 5.

- Non-metastatic (M0)

AND EITHER

- node positive (N1)

OR

- node negative (N0) with one of either:
  - a PSA concentration ≥4 nanograms/ml with a doubling time of <6 months
  - a PSA concentration ≥20 nanograms/ml).

About current standard care

Patients with high-risk non-metastatic cancer are almost all offered radical, external beam radiotherapy to the prostate. Brachytherapy boost may be offered alongside external beam radiotherapy. Patients are started on hormone therapy known as androgen deprivation therapy (ADT) three to six months prior to commencing radiotherapy and continue for up to 36 months. ADT, radiotherapy and brachytherapy are the only treatments currently commissioned by NHS England for high-risk, non-metastatic prostate cancer. A very small number of highly selected patients with high-risk disease may alternatively have radical prostatectomy. These patients would not be given systemic hormonal therapy.

About abiraterone acetate

Abiraterone acetate is an anti-androgen treatment that is licensed in adults for the treatment of metastatic prostate cancer. It works by inhibiting enzymes involved in the testosterone production pathway, thus reducing circulating levels of testosterone, when used in combination with ADT. It is administered orally in combination with prednisolone in a once daily regime.

The use of abiraterone acetate in high-risk, non-metastatic prostate cancer is an off-label use of the drug.

Epidemiology and needs assessment

There are roughly 44,300 new cases of prostate cancer every year in England. Anecdotal evidence suggests that 15-20% of newly diagnosed prostate cancer patients would be high risk non-metastatic at diagnosis. Of these, 90% are likely to meet the eligibility criteria and so benefit from this policy. This would equate to on average 6977 patients per year.

Implementation

Inclusion criteria[3]

All patients with newly diagnosed high-risk, hormone sensitive prostate cancer or relapsing prostate cancer with high-risk features planned for standard of care treatment with radiotherapy (unless contraindicated) who meet the following eligibility criteria.

[3] The evidence informing the development of this policy comes from a clinical trial where patients were staged according to images obtained from CT, MRI and bone scans.

Newly diagnosed high-risk prostate cancer

Eligible patients are defined as:

- WHO performance status 0-2

  AND

- Non-metastatic (M0)

  AND EITHER

- Pelvic node positive (N1)

  OR

- Node negative (N0) with at least two of:
  - tumour stage T3 or T4
  - Gleason score 8-10
  - Prostate specific antigen (PSA) ≥ 40 nanograms/ml

Relapsing prostate cancer with high-risk features

Eligible patients are defined as previously radically treated prostate cancer with an interval of ≥12 months without treatment and:

- WHO performance status 0-2

  AND

- Non-metastatic (M0)

  AND EITHER

- Pelvic node positive (N1)

  OR

- Node negative (N0) with one of either:
  - a PSA concentration ≥4 nanograms/ml with a doubling time of <6 months
  - a PSA concentration ≥20 nanograms/ml).

Exclusion criteria

All patients who meet any of the following exclusion criteria are not eligible for treatment with abiraterone acetate and prednisolone under this policy:

- patients with contraindications to abiraterone acetate, as outlined in the summary of product characteristics (SmPC)
- patients with confirmed clinically significant cardiovascular disease[4]

Starting criteria

Patients should have been appropriately assessed, including PSA, staging scans and biopsy to confirm high-risk status and exclude metastatic disease.

[4] Significant cardiovascular disease may include severe angina, recent myocardial infarction or a history of cardiac failure (Attard et al, 2022)

All patients should be discussed at a prostate multidisciplinary team (MDT) meeting prior to starting treatment.

Patients should be started on ADT prior to starting abiraterone and continue throughout the course.

Stopping criteria

Treatment with abiraterone acetate and prednisolone should be given for a total of two years.

A decision to stop[5] using abiraterone acetate and prednisolone before two years should be made by the treating clinician if one of the following occur:

- a serious adverse event or general intolerance related to treatment **OR**
- evidence of disease progression despite treatment **OR**
- informed decision to stop treatment.

Monitoring

Serum transaminases should be measured prior to starting treatment, every two weeks for the first three months of treatment and monthly thereafter. Blood pressure, serum potassium and fluid retention should be monitored monthly. However, patients with a significant risk for congestive heart failure should be monitored every two weeks for the first three months of treatment and monthly thereafter.

PSA levels should be monitored, and any required imaging should be done if the treating clinician deems necessary.

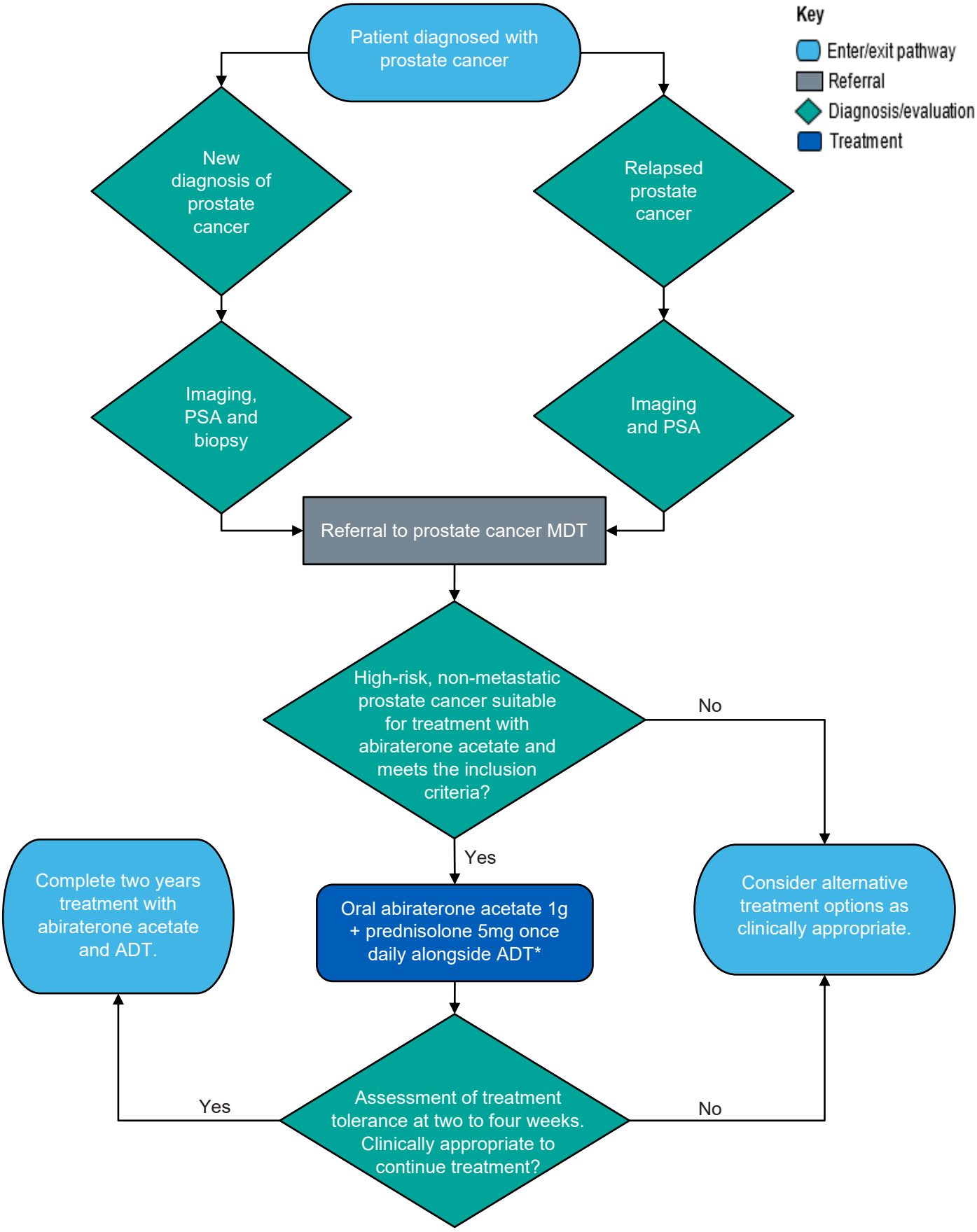
Dose

The use of abiraterone acetate for high-risk, non-metastatic prostate cancer is off-label and Trust policy regarding off-label use of medicines should apply.

Oral abiraterone acetate should be given as a once daily dose of 1g alongside 5mg of prednisolone. These should be taken in combination with ADT therapy.

[5] Patients may continue ADT for the planned duration of treatment after stopping abiraterone acetate

Patient pathway



*Patients should be started on ADT prior to starting abiraterone.

Governance arrangements

Provider organisations must register all patients using prior approval software and ensure monitoring arrangements are in place to demonstrate compliance against the criteria as outlined.

The use of abiraterone acetate is off-label; Trust policy regarding unlicensed medicines should apply.

Any provider organisation treating patients with this intervention will be required to assure itself that the internal governance arrangements have been completed before the medicine is prescribed. These arrangements may be through the Trust's Drugs and Therapeutics committee (or similar) and NHS England may ask for assurance of this process.

Mechanism for funding

Abiraterone acetate and prednisolone will be commissioned and funded by NHS England Specialised Commissioning under existing arrangements for the provision of Specialised Cancer and Chemotherapy services.

Audit requirements

Data will be reviewed through use of prior approval forms.

Policy review date

This document will be reviewed when information is received which indicates that the policy requires revision. If a review is needed due to a new evidence base then a new Preliminary Policy Proposal needs to be submitted by contacting england.CET@nhs.net.

Our policies provide access on the basis that the prices of therapies will be at or below the prices and commercial terms submitted for consideration at the time evaluated. NHS England reserves the right to review policies where the supplier of an intervention is no longer willing to supply the treatment to the NHS at or below this price and to review policies where the supplier is unable or unwilling to match price reductions in alternative therapies.

Equality statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Definitions

Metastatic	Cancer that spreads from where it started to a distant part of the body is called metastatic cancer. For many types of cancer, it is also called stage IV (4) cancer. The process by which cancer cells spread to other parts of the body is called metastasis.
The National Institute for Health and Care Excellence (NICE)	NICE provides national guidance and advice to improve health and social care. NICE is an executive non-departmental public body, sponsored by the Department of Health and Social Care.
PSA	Prostate specific antigen is a protein produced by normal prostate glands. The PSA level can be measured by a blood test. A small amount of PSA in the blood is normal. If the prostate becomes enlarged, inflamed, or infected, larger amounts of PSA get into the blood. The amount of PSA in the blood may also increase if there is cancer in the prostate.
The WHO performance status	The WHO performance status classification categorises patients as: 0. Able to carry out all normal activity without restriction 1. Restricted in strenuous activity but ambulatory and able to carry out light work 2. Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours 3. Symptomatic and in a chair or in bed for greater than 50% of the day but not bedridden 4. Completely disabled; cannot carry out any self-care; totally confined to bed or chair.

References

Attard G, Murphy L, Clarke NW, Cross W, Jones RJ, Parker CC, et al. Abiraterone acetate and prednisolone with or without enzalutamide for high-risk non-metastatic prostate cancer: a meta-analysis of primary results from two randomised controlled phase 3 trials of the STAMPEDE platform protocol. Lancet 2022;399(10323):447-60

Cancer Research UK. 2022. Prostate cancer statistics. [online] Available at: <https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/prostate-cancer#heading-Zero> [Accessed 13 September 2022].

Crukcancerintelligence.shinyapps.io. 2022. Early Diagnosis. [online] Available at: <https://crukcancerintelligence.shinyapps.io/EarlyDiagnosis/> [Accessed 15 September 2022].

James, N.D. et al. (2022) 'Docetaxel for nonmetastatic prostate cancer: Long-term survival outcomes in the Stampede Randomized Controlled Trial', JNCI Cancer Spectrum, 6(4). doi:10.1093/jncics/pkac043.

Overview: Prostate cancer: Diagnosis and management: Guidance (2021) NICE. Available at: https://www.nice.org.uk/guidance/NG131 [Accessed: 03 May 2023].

Appendix A

This policy relates to the following:

Service Specifications

- NHS England Commissioning Service Specification: Positron Emission Tomography – Computed Tomography (PET CT) Scanning (All Ages)

NHS England Clinical Commissioning Policies

- Brachytherapy dose escalation with external beam radiotherapy for intermediate- and high-risk localised prostate cancer
- External beam radiotherapy for patients presenting with hormone sensitive, low volume metastatic prostate cancer at the time of diagnosis
- External beam radiotherapy for patients presenting with hormone sensitive, low volume metastatic prostate cancer at the time of diagnosis
- Robotic assisted surgical procedures for prostate cancer

NHS England Commissioning Policy Statements

- Positron Emission Tomography- Computed Tomography (PET-CT) Guidelines (all ages)
- Docetaxel in combination with androgen deprivation therapy for the treatment of hormone naïve metastatic prostate cancer

Not Routinely Commissioned Clinical Policies

- Proton beam therapy for cancer of the prostate
- Stereotactic ablative radiotherapy in the treatment of prostate cancer

NICE Technology Appraisals

- Enzalutamide for treating hormone-sensitive metastatic prostate cancer (TA712)
- Degarelix for treating advanced hormone-dependent prostate cancer (TA404)
- Darolutamide with androgen deprivation therapy for treating hormone-relapsed non-metastatic prostate cancer (TA660)
- Apalutamide with androgen deprivation therapy for treating hormone-sensitive metastatic prostate cancer (TA741)
- Darolutamide with androgen deprivation therapy and docetaxel for treating hormone-sensitive metastatic prostate cancer (TA903)
- Docetaxel for the treatment of hormone-refractory metastatic prostate cancer (TA101)
- Apalutamide with androgen deprivation therapy for treating high-risk hormone-relapsed non-metastatic prostate cancer (TA740)
- Enzalutamide for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated (TA377)
- Olaparib for previously treated BRCA mutation-positive hormone-relapsed metastatic prostate cancer (TA887)

- Abiraterone for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen (TA259)
- Abiraterone for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated (TA387)
- Cabazitaxel for hormone-relapsed metastatic prostate cancer treated with docetaxel (TA391)
- Enzalutamide for metastatic hormonerelapsed prostate cancer previously treated with a docetaxelcontaining regimen (TA316)
- Radium-223 dichloride for treating hormone-relapsed prostate cancer with bone metastases (TA412)

Negative NICE Technology Appraisals

- Padeliporfin for untreated localised prostate cancer (TA546)
- Enzalutamide for hormone-relapsed non-metastatic prostate cancer (TA580)
- Abiraterone for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer (TA721)