Reference no: 2424
Publication date: 13 December 2024

Interim clinical commissioning policy proposition:

Abiraterone acetate and prednisolone for high-risk, hormone-sensitive metastatic prostate cancer (adults) [2424]

Summary

The proposition is: abiraterone acetate and prednisolone are recommended to be available as a routine commissioning treatment option within the criteria set out in this document for newly diagnosed high-risk hormone-sensitive metastatic prostate cancer.

The use of abiraterone acetate is licensed for newly diagnosed high-risk hormone-sensitive metastatic prostate cancer in combination with androgen deprivation therapy (ADT).

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

This is an interim clinical commissioning policy pending the outcome of a NICE evaluation of the use of generic abiraterone acetate in this high-risk hormone-sensitive metastatic prostate cancer population.

Committee discussion

Clinical Panel agreed with the proposition and recommended this proceed as a routine commissioning proposition.

What we have decided

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

The evidence of clinical effectiveness for abiraterone acetate and prednisolone in this population is documented in NICE Technology Appraisal 721.

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'. Prostate cancer grade can be assessed and risk stratified with a Gleason score (a pathology grade from six to ten 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). The International Society of Urological Pathology (ISUP) grades incorporate Gleason scoring into a newer system of setting into groups 1-5 and also 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.

Newly diagnosed high-risk hormone-sensitive metastatic prostate cancer would be classified as having **at least 2** of the following factors[2]:

- a Gleason score of ≥ 8
- presence of ≥ 3 bone metastases on conventional imaging (CT scan or isotope bone scan)
- the presence of visceral metastasis on conventional imaging (CT scan) (excluding lymph node disease)

About current standard care

Patients with newly diagnosed hormone-sensitive metastatic prostate cancer are currently offered:

- ADT alone **OR**
- Docetaxel plus ADT **OR**
- Docetaxel plus darolutamide and ADT **OR**
- Enzalutamide and ADT **OR**
- Apalutamide plus ADT.

Choice of which of these options depends on all of the following: the wishes of the patient, the fitness of the patient, any relevant comorbidities and concurrent medications and on the differing licensing of the androgen receptor inhibitors in hormone-sensitive metastatic prostate cancer (enzalutamide, apalutamide and darolutamide).

[1] In this policy proposition the term 'men' is used, based on the source evidence used in its development. This proposition is also relevant to people with male anatomy who do not identify as men.
[2] As defined in the LATITUDE trial.

About abiraterone acetate

Abiraterone acetate plus prednisolone is an anti-androgen treatment that is licensed in combination with ADT in adults for the treatment of newly diagnosed high-risk hormone-sensitive 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.

Epidemiology and needs assessment

There are approximately 44,000 new cases of prostate cancer every year in England (Cancer Research, 2024). On average, 18% of these new cases are diagnosed at stage IV (metastatic cancer) (National Disease Registration Service).

In the population of patients with newly diagnosed high-risk hormone-sensitive metastatic prostate cancer, approximately 5200 patients per year receive current commissioned first line treatments of enzalutamide or apalutamide. It is estimated that 30% of these patients (approximately 1560 patients) would benefit from this policy proposition per year in England.

Implementation

Inclusion criteria

All patients who are planned for standard of care treatment who have **EITHER**:

- A diagnosis of newly diagnosed high-risk metastatic hormone-sensitive prostate cancer[3]

OR

- Patients who were enrolled in the STAMPEDE trial with hormone-sensitive prostate cancer and who are continuing to derive benefits from maintained long term abiraterone therapy (this also includes patients with high-risk locally advanced disease who were enrolled in the STAMPEDE trial)[4]

AND

- World Health Organisation (WHO) or Eastern Cooperative Oncology Group (ECOG) performance status 0-2

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 proposition:

- patients with contraindications to abiraterone acetate, as outlined in the summary of product characteristics (SmPC)

[3]Includes patients who are commenced on alternative first line treatment which had to be stopped because of dose-limiting toxicity in the clear absence of disease progression and the patient meets all the other criteria listed here.

[4] The use of abiraterone acetate in this patient cohort is off-label and Trust policy regarding off-label use of medicines should apply.

Starting criteria

Patients must meet the inclusion criteria as outlined in this policy document before initiation initiating treatment.

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

Stopping criteria

Treatment with abiraterone acetate and prednisolone should be given until disease progression or unacceptable toxicity or withdrawal of patient consent.

Monitoring

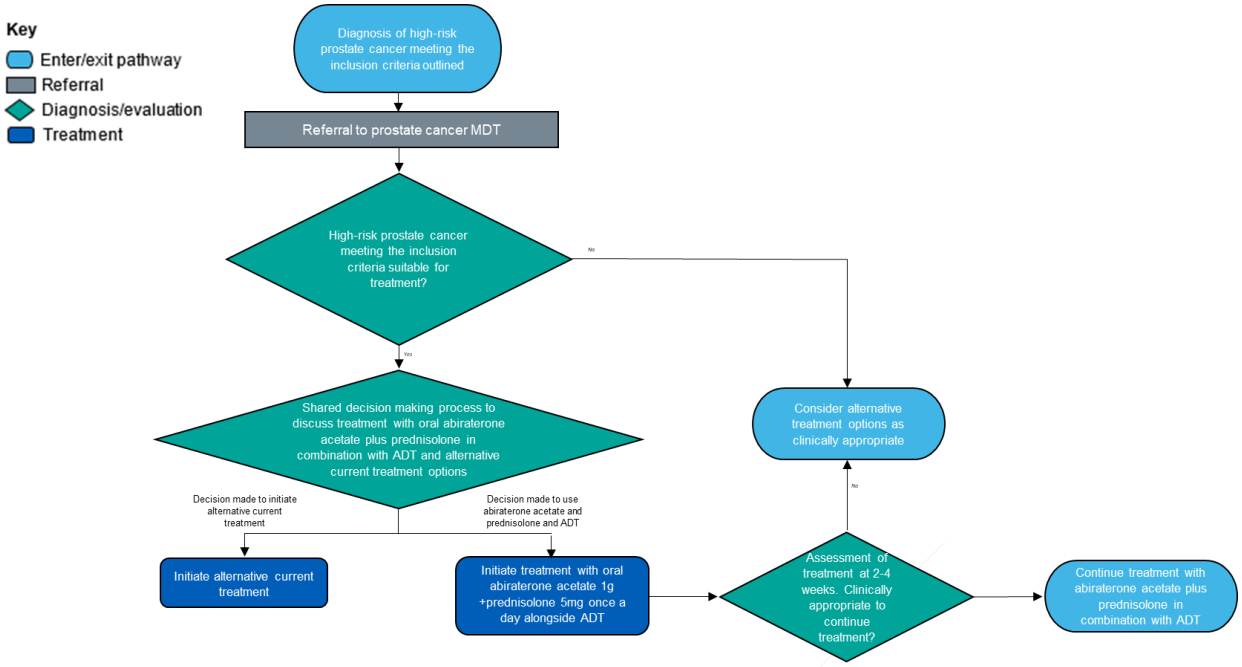
Patients should be monitored as per the requirements outlined in the SmPC.

Dose

The use of abiraterone acetate plus prednisolone in combination with ADT is licensed for newly diagnosed high-risk metastatic hormone-sensitive prostate cancer.

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.

Patient pathway



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 plus prednisolone in combination with ADT is licensed for newly diagnosed high-risk hormone-sensitive metastatic prostate cancer.

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 NICE has completed its review of Technology Appraisal 721: Abiraterone for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer.

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

Abiraterone for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer (2021) NICE. Available at: https://www.nice.org.uk/guidance/ta721 [Accessed: 12 November 2024].

Cancer Research UK. 2024. Prostate cancer statistics. [online] Available at: https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/prostate-cancer [Accessed 12 November 2024].

Fizazi, K., Tran, N., Fein, L., Matsubara, N., Rodriguez-Antolin, A., Alekseev, B.Y., Özgüroğlu, M., Ye, D., Feyerabend, S., Protheroe, A. and Sulur, G., 2019. Abiraterone acetate plus prednisone in patients with newly diagnosed high-risk metastatic castration-sensitive prostate cancer (LATITUDE): final overall survival analysis of a randomised, double-blind, phase 3 trial. The Lancet Oncology, 20(5), pp.686-70

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:

NHS England Commissioning Policy Statements

- Docetaxel in combination with androgen deprivation therapy for the treatment of hormone naïve metastatic prostate cancer

NICE Technology Appraisals

- Enzalutamide for treating hormone-sensitive metastatic prostate cancer (TA712)
- Degarelix for treating advanced hormone-dependent prostate cancer (TA404)
- 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)

Negative NICE Technology Appraisals

- Abiraterone for treating newly diagnosed high-risk hormone-sensitive metastatic prostate cancer (TA721)