Engagement report

Topic details

Title of policy or policy statement:	Abiraterone acetate and prednisolone for high-risk, hormone sensitive, non-metastatic prostate cancer (adults)
Programme of Care:	Cancer
Clinical Reference Group:	Chemotherapy
URN:	2312

1. Summary

This report summarises the feedback NHS England received from engagement during the development of this policy proposition, and how this feedback has been considered.

2. Background

Prostate cancer is the most common cancer in men 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 African-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.

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.

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. Abiraterone acetate is proposed for patients with high-risk,

hormone sensitive, non-metastatic prostate cancer (newly diagnosed high-risk or relapsing with high-risk features).

3. Engagement

NHS England has a duty under Section 13Q of the NHS Act 2006 (as amended) to 'make arrangements' to involve the public in commissioning. Full guidance is available in the Statement of Arrangements and Guidance on Patient and Public Participation in Commissioning. In addition, NHS England has a legal duty to promote equality under the Equality Act (2010) and reduce health inequalities under the Health and Social Care Act (2012).

The policy proposition underwent a two-week stakeholder testing between the 30th November and 14th December 2023 with registered stakeholders from the following Clinical Reference Groups:

- Chemotherapy
- Radiotherapy

The comments have then been shared with the Policy Working Group to enable full consideration of feedback and to support a decision on whether any changes to the proposition might be recommended.

Respondents were asked the following consultation questions:

- Do you believe that there is any additional information that we should have considered in the evidence review?
- Do you support the inclusion criteria set out in the policy proposition?
- Do you support the exclusion criteria set out in the policy proposition?
- Do you have any further comments on the proposal?
- Do you support the Equality and Health Inequalities Impact Assessment?
- Does the Patient Impact Summary present a true reflection of the patient and carers lived experience of this condition?
- Please declare any conflict of interests relating to this document or service area.

A 13Q assessment has been completed following stakeholder testing.

The Programme of Care (PoC) has decided that the proposition offers a clear and positive impact on patient treatment, by potentially making a new treatment available which widens the range of treatment options without disrupting current care or limiting patient choice, and therefore further public consultation was not required. This decision has been assured by the Patient Public Voice Advisory Group.

4. Engagement Results

14 stakeholders responded:

- 8 Clinicians
- 1 patient
- 1 professional association
- 2 NHS Trusts
- 2 prostate cancer charities

5. How has feedback been considered?

Responses to engagement have been reviewed by the Policy Working Group and the Cancer PoC. The following themes were raised during engagement:

Keys themes in feedback	NHS England Response
Relevant Evidence	
All stakeholders were satisfied that the relevant was considered and no additional evidence was identified. One stakeholder was concerned that the cost effectiveness study included in the evidence review did not take account of abiraterone acetate now being available as a generic formulation and therefore cheaper than branded abiraterone acetate.	Noted. The independent evidence review only includes evidence published in peer reviewed journals. NHS England will take into account the lowest acquisition cost of abiraterone acetate when developing the financial model for this policy proposition.
Inclusion/ exclusion criteria	
All stakeholders supported the policy inclusion and exclusion criteria. One stakeholder was concerned that the inclusion criteria does not cover those with Cambridge Prognostic Group 5 staged prostate cancer.	Noted. The inclusion criteria have been based off the findings from the evidence review, which came from the STAMPEDE trial. At this stage there is insufficient data to evidence safe and effective use of abiraterone in patients who do not meet the STAMPEDE inclusion criteria.
Current Patient Pathway	
One stakeholder was concerned about the level of service provision, were abiraterone to be funded, as this would increase pressures and demands on the existing service.	Noted. As a delegated service, Integrated Care Boards would be responsible for implementing a service that is able to support the delivery of nationally commissioned treatments. This will be taken into account in the commissioning plan.
Potential impact on equality and health inequalities	
One stakeholder was concerned about regional implementation of the policy and wanted to ensure all regions adopted the policy.	Noted. As a delegated service, Integrated Care Boards would be responsible for implementing a service that is able to support the delivery of nationally commissioned treatments. This will be taken into account in the commissioning plan.

Changes/addition to policy	
One stakeholder suggested less frequent monitoring of the patients' liver function tests and blood pressure.	The monitoring criteria have been taken directly from the Summary of Product Characteristics (SmPC) for abiraterone acetate.

6. Has anything been changed in the policy proposition as a result of the stakeholder testing and consultation?

The following change(s) based on the engagement responses has (have) been made to the policy proposition:

No changes have been made.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

No.