NHS England Specialised Services

Clinical Panel report

Date: 15th November 2023

Intervention: Abiraterone acetate and prednisolone

Indication: for high-risk, hormone sensitive, non-metastatic prostate cancer (adults)

URN: 2312

Gateway: 2, Round 1

Programme: Cancer

CRG: Chemotherapy

Information provided to the Panel

Policy Proposition

Evidence Review completed by Solutions for Public Health

Clinical Priorities Advisory Group (CPAG) Summary Report

Evidence to Decision Summary

Equalities and Health Inequalities (EHIA) Assessment

Patient Impact Assessment

Blueteq™ Report

Policy Working Group (PWG) Appendix

This Policy Proposition recommends the use of abiraterone acetate and prednisolone for adult patients with high-risk, hormone-sensitive, non-metastatic prostate cancer. This proposition is restricted to adults only as prostate cancer is very rare in children. Prostate cancer is the most common cancer in people with a prostate in the UK, with an incidence of over 45,000 each year. Roughly 15-20% of all newly diagnosed prostate cancers are high-risk. High risk prostate cancer can progress quickly, has poorer survival outcomes, and a greater risk of relapse. The current standard care pathway involves androgen deprivation therapy (ADT) alone and external beam radiotherapy. Abiraterone acetate is an oral anti-androgen treatment prescribed in combination with prednisolone.

The proposition and the supporting evidence review were presented to Panel members. Five studies were included in the evidence review, including a multi-arm, multi-stage, multi-centre platform randomised controlled trial (STAMPEDE), published in four papers. A fifth paper reported cost effectiveness.

The critical outcomes for clinical effectiveness were overall survival (OS), metastasis-free survival (MFS), progression free survival (PFS). Identified important outcomes were reported also, which included Quality of Life (QoL). The presentation to Panel members covered all

elements of the evidence. The evidence presented across all critical and important outcomes was reported from high to very low using GRADE.

The RCT provided data comparing AAP plus ADT to ADT for the critical outcomes of OS, MFS and PFS. These reported a statistically significant advantage for AAP plus ADT for outcomes reported at a median of 85 months follow-up. For outcomes reported at a median of 40 months follow-up there was also a statistically significant advantage for failure-free survival (PFS including biochemical failure) but not for OS. In terms of QoL, no evidence relating to quality of life was identified for AAP & ADT compared to ADT or when compared with ADT and docetaxel. AAP and ADT was not considered cost effective using the 2017/18 published price.

Limitations of the studies presented were discussed. Panel members agreed that a clinical benefit can be seen regarding impact on survival without increasing the level of disease.

The proposition and supporting documents were considered and some amendments requested.

EHIA – an amendment was requested.

Recommendation

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

Why the panel made these recommendations

The evidence and reported outcomes were considered carefully. Panel members agreed that a clear benefit can be seen regarding impact on survival without increasing the level of disease.

Documentation amendments required

General

- Standardise the title of the proposition across all documentation for consistency.

Policy Proposition:

- Should the title include ‘or relapsing’ as it currently doesn’t match what is in the proposition appreciating the title will then be very long. It needs at least to be included at the beginning of the document.
- Current standard of care section – consider removing the reference to docetaxel not being commissioned. Panel members found this confusing.
- About abiraterone acetate section - add a sentence that abiraterone acetate is for high-risk prostate cancer and that it is off-label so it is clear. It is mentioned in the governance section but needs to be referenced earlier in the proposition.
- Inclusion criteria –
    - Page 4 – the WHO performance status is included but this is not mentioned in anywhere in definition of high-risk prostate cancer.
    - superscript reference to relapsing – change to normal format? The use of ‘could’ is too loose a term and needs to be stated as ‘is’.
- Monitoring – clearer reference needs to be made regarding the monitoring of congestive cardiac failure.
- Pathway – Relapsing needs to be included in the pathway.

EHIA:

- Pg 12 – remove reference to sarcoidosis.

Declarations of Interest of Panel Members: One received due to clinical practice.

Panel Chair: James Palmer, Medical Director, Specialised Services

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Actioned amendments:

General

- Standardise the title of the proposition across all documentation for consistency.
  Actioned. Title for all documents should read:
  'Abiraterone acetate and prednisolone for high-risk, hormone sensitive, non-metastatic prostate cancer (adults)'.

Policy Proposition:

- Should the title include 'or relapsing' as it currently doesn't match what is in the proposition appreciating the title will then be very long. It needs at least to be included at the beginning of the document.

  Actioned. The summary of the policy proposition now reads:

  'The proposition is: 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.'

- Current standard of care section – consider removing the reference to docetaxel not being commissioned. Panel members found this confusing.

  Actioned.

- About abiraterone acetate section - add a sentence that abiraterone acetate is for high-risk prostate cancer and that it is off-label so it is clear. It is mentioned in the governance section but needs to be referenced earlier in the proposition.

  Actioned.

- Inclusion criteria –
  - Page 4 – the WHO performance status is included but this is not mentioned in anywhere in definition of high-risk prostate cancer.

    The definition on page 2 is the definition of high-risk prostate cancer in terms of staging. The inclusion criteria on page 3 outline those who are eligible to receive abiraterone acetate according to this policy. The inclusion criteria are not defining high risk prostate cancer but rather eligible patients.
  - superscript reference to relapsing – change to normal format? The use of 'could' is too loose a term and needs to be stated as 'is'.

    Actioned.

    The inclusion criteria have now been separated out into 'newly diagnosed high-risk' and 'relapsing with high-risk features' for clarity.

- Monitoring – clearer reference needs to be made regarding the monitoring of congestive cardiac failure.

Unsure what this means. The policy currently reads:

'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.' This is as per the SmPC and the STAMPEDE trial.

- Pathway – Relapsing needs to be included in the pathway.

  Actioned.

  Pathway split into two entry points for clarity.

EHIA:

- Pg 12 – remove reference to sarcoidosis.

Actioned.