NHS England specialised service

Clinical panel report

Date: 18th October 2023

Intervention: Prostate specific membrane antigen radiotracers (PSMA) in Positron Emission Tomography-Computed Tomography (PET-CT) imaging

Indication: individuals with high-risk primary or recurrent prostate cancer

URN: 2307

Gateway: 2, Round 1

Programme: Cancer

CRG: Nuclear Medicine Respond and Advise

Information provided to the Panel

Commissioning Policy Proposition

Two three-paper evidence summaries completed by Solutions for Public Health – high risk prostate cancer and recurrent prostate cancer

Clinical Priorities Advisory Group (CPAG) Summary Report x2

Equalities and Health Inequalities (EHIA) Assessment

Blueteq™ Report

Policy Working Group (PWG) appendix

This Commissioning Policy Proposition recommends the use of PSMA PET-CT radiotracers commissioned by NHS England for patients with high-risk primary prostate cancer or biochemical recurrence. NHS England currently commissions choline radiotracers for PET-CT in prostate cancer. In 2019, due to the breakdown of the choline supply chain, an interim commissioning position allowed the reimbursement of two alternative radiotracers in prostate cancer – galliuma68-Prostate Specific Membrane Antigen (PSMA) and fluorine18-PSMA. PSMA radiotracers work by targeting the PSMA protein which is only expressed by prostate cancer cells. If approved, this commissioning policy proposition will supersede the current interim commissioning position for reimbursement of PSMA radiotracers.

The proposition and the supporting evidence summaries were presented to Panel members.

Three studies were summarised for high-risk prostate cancer which included a randomised controlled trial (n=302), a prospective single arm diagnostic efficacy trial (n=764), and a retrospective case series (n=116). Outcomes reported included accuracy of imaging, reporter agreement, equivocal findings, changing of staging and patient management, radiation exposure, biochemical recurrence, and safety. Statistically significant differences with the use of ^{68}Ga-PSMA-11 PET-CT compared with conventional imaging were reported in accuracy of imaging, equivocal findings, change in patient management and radiation exposure. Improvements were identified across the other reported outcomes, with no adverse events graded 2 or higher.

Three studies were summarised for recurrent prostate cancer which included a prospective single arm comparative trial (n=50), a prospective open-label cross-over study (n=195), and a prospective single arm trial (n=382). Outcomes reported included detection rates, validation of PET-CT findings, patient management, impact of PET-CT scans on diagnostic tests, reporter agreement, and safety. Statistically significant differences were reported in detection rates across two trials. A greater proportion of changes to diagnostic thinking was reported with fewer tests required, and major changes made to patient management. No serious adverse events reported.

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

EHIA – no amendments requested.

Recommendation

Clinical Panel agreed with the proposition and recommended this proceeds as a routine commissioning proposition. It was agreed that the requested revisions to the proposition would be approved via Chair's action with support from two members of Panel.

Why the panel made these recommendations

The evidence and reported outcomes were considered carefully. Panel members agreed that sufficient clinical benefits were demonstrated to support the commissioning position.

Documentation amendments required

Policy Proposition:

- The wording regarding licensed/unlicensed products needs to be checked to ensure correctness.
- Inclusion criteria –
    - Section 1 – the Gleason score is currently stated as >8. Panel members queried whether this should read >7 or ≥8. To clarify with the PWG.
    - Section 2 – the second sentence needs to be reviewed as it was thought that a PSA <0.2ng/ml would be too low to consider. To clarify with the PWG.

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

Panel Chair: Anthony Kessel, Clinical Director, National Clinical Policy, Specialised Commissioning