

Engagement report

Topic details

Title of policy or policy statement:	Prostate-Specific Membrane Antigen (PSMA) radiotracers in Positron Emission Tomography – Computerised Tomography (PET-CT) in prostate cancer
Programme of Care:	Cancer
Clinical Reference Group:	Radiotherapy
URN:	2307

1. Summary

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

2. Background

The prostate is a small gland located at the base of the bladder. Prostate cancer only affects men¹; this means that this policy applies to any person with a prostate. Prostate cancer is the most common type of cancer in men and the second most common type of cancer in the UK. This commissioning policy proposition concerns two distinct subgroups of patients with prostate cancer: those with high-risk primary disease suitable for radical, curative treatment and those with biochemical recurrence suitable for salvage therapy.

Positron Emission Tomography (PET) – Computerised Tomography (CT) is a unique imaging tool which shows pathology by using PET to detect abnormal tissue metabolism and CT to show structural changes. PET-CT uses small amounts of radioactive materials called radiotracers. The radiotracers collect within tissues and help identify abnormal metabolic activity, allowing early and precise identification of disease spread.

PET-CT is commissioned for use along the prostate cancer pathway, specifically to support cancer staging, and to assess whether the cancer has returned (recurrence). Under certain criteria, PET-CT is more specific and sensitive in identifying early metastatic disease than conventional imaging. Early identification of metastatic foci with PET-CT enables optimal treatment decisions to be made and can alter the planned treatment choice.

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.

This commissioning policy proposition sets out the eligibility criteria for PSMA PET-CT radiotracers commissioned by NHS England for patients with high-risk primary prostate cancer or biochemical recurrence. This commissioning policy proposition will supersede the current interim commissioning position for reimbursement of PSMA radiotracers. Commissioned providers may use Ga68-PSMA, F18-PSMA or choline radiotracers for PET-CT depending on availability and supply.

PSMA radiotracers work by targeting the PSMA protein which is only expressed by prostate cancer cells. PSMA is overexpressed in 95% of prostate cancer cells but the overexpression of PSMA has not been found in benign prostatic diseases such as prostatic hyperplasia. Although the target is the same, both Ga68-PSMA and F18-PSMA have slightly different imaging characteristics. Both Ga68-PSMA and F18-PSMA are unlicensed products.

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 30th October to 14th November 2023 with registered stakeholders from the following Clinical Reference Groups:

- Chemotherapy
- Specialised cancer surgery
- Radiotherapy
- Cancer Diagnostics Special Interest Group stakeholder list

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 support the Equality and Health Inequalities Impact Assessment?
- Do the evidence summaries support the commissioning criteria?
- Do you agree with the policy inclusion criteria?
- Do you agree with the policy exclusion criteria?
- Does the Patient Impact Assessment (PIA) present a true reflection of the patient and carers lived experience of this condition?
- Do you have any further comments on the policy proposal? If so, please submit these in under 500 words.

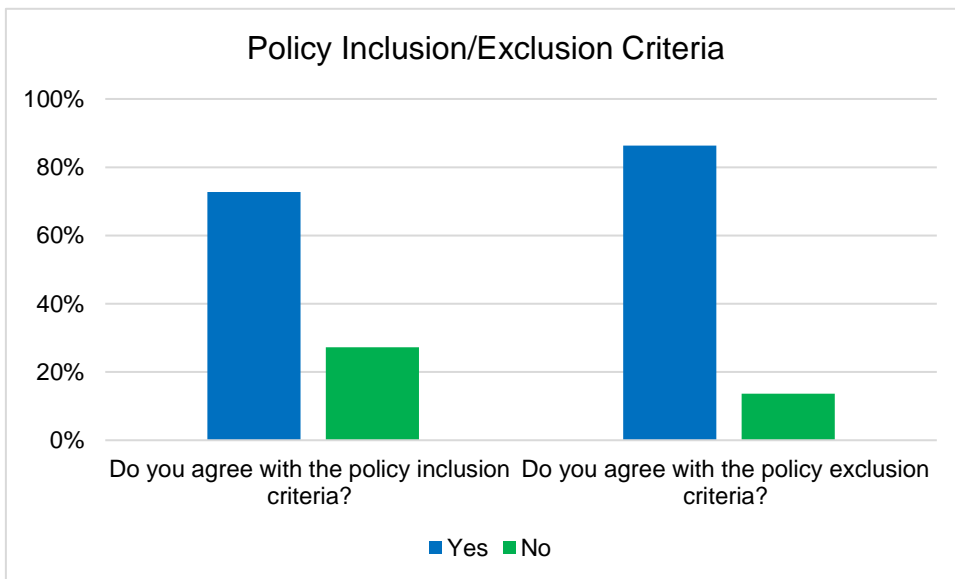
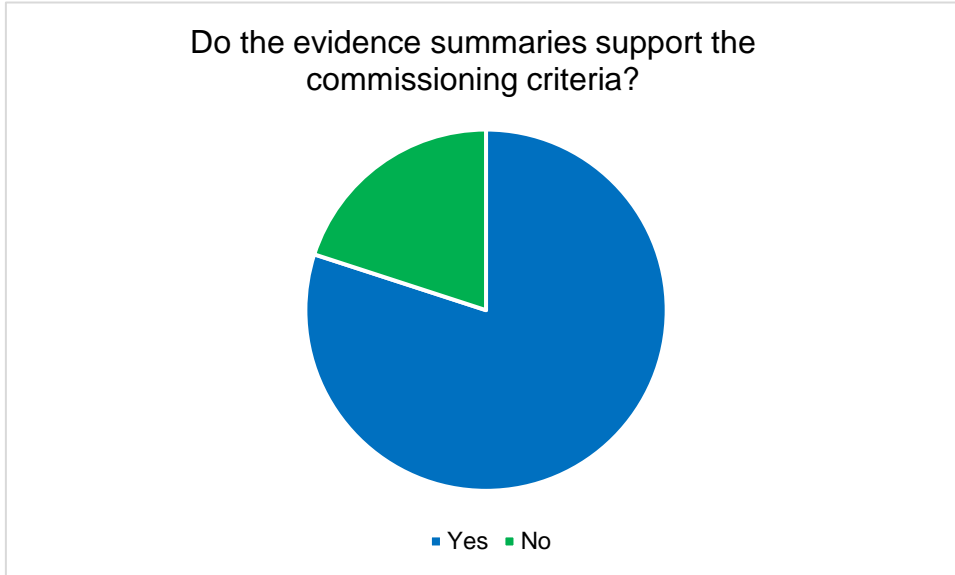
A 13Q assessment has been completed following stakeholder testing.

The Programme of Care 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

26 stakeholders responded:

- 15 Clinicians
- 1 Commissioner
- 8 NHS Trusts
- 1 Society
- 1 Supplier



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	
Majority of stakeholders agreed that the evidence in the three paper summaries supported the commissioning criteria. Some stakeholders felt that the criteria for commissioning PSMA PET-CT	This position is in line with NHS England's current commissioning position for choline radiotracer for prostate cancer as well as the Royal

should be widened to all patients with high-risk prostate cancer, and identified additional papers:

1. Afaq A, Payne H et al. A Phase II, Open-label study to assess safety and management change using ⁶⁸Ga-THP PSMA PET/CT in patients with high risk primary prostate cancer or biochemical recurrence after radical treatment: The PRONOUNCED study. *J Nucl Med.* 2021; 62: 1727–1734.
2. BNMS. PET-CT Tracer Commissioning Manifesto. September 2023
3. de Feria Cardet R, Hofman M et al. Is Prostate-specific Membrane Antigen Positron Emission Tomography/Computed Tomography Imaging Cost-effective in Prostate Cancer: An Analysis Informed by the proPSMA Trial. *Eur Urol.* 2021; 79: 413–418.
4. Ferraro D, Garcia Schüler H et al. Impact of ⁶⁸Ga-PSMA-11 PET staging on clinical decision-making in patients with intermediate or high-risk prostate cancer. *Eur J Nucl Med Mol Imaging.* 2020; 47(3): 652-664.
5. Hofman M, Lawrentschuk N et al. Prostate-specific membrane antigen PET-CT in patients with high-risk prostate cancer before curative-intent surgery or radiotherapy (proPSMA): a prospective, randomised, multicentre study. *Lancet.* 2020; 395: 1208–1216.
6. Kulkarni M, Hughes S et al. The management impact of ⁶⁸gallium-tris(hydroxypyridinone) prostate-specific membrane antigen (⁶⁸Ga-THP-PSMA) PET-CT imaging for high-risk and biochemically recurrent prostate cancer. *Eur J Nucl Med Mol Imaging.* 2020; 47: 674–686.

College of Radiologist PET-CT guidelines.

The additional papers identified do not make a material difference to the policy (please see the separate public health report).

Policy inclusion/exclusion criteria	
<p>Majority of stakeholders agreed with the policy inclusion and exclusion criteria.</p> <p>Some stakeholders felt that PSMA PET-CT should be offered to all patients with high-risk prostate cancer as a first line imaging modality.</p>	<p>This commissioning position has been created as a formative position to the current interim commissioning statement for PSMA PET-CT.</p> <p>This position is in line with NHS England's current commissioning position for choline radiotracer for prostate cancer as well as the Royal College of Radiologist PET-CT guidelines.</p> <p>This commissioning policy was not intended to broaden the current commissioning criteria but align with what was being commissioned in the interim.</p>
Potential impact on equality and health inequalities	
<p>All patients agreed with the equalities and health inequalities impact assessment.</p> <p>One stakeholder was concerned that PSMA PET-CT is not currently available in all centres in the UK, creating a post-code lottery.</p>	<p>Noted.</p> <p>This commissioning policy should increase equity of access to PSMA PET-CT as centres invest in PSMA.</p>
Changes/addition to policy	
<p>No material changes or additions to the policy were identified.</p>	<p>No further action required.</p>

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

No changes have been made to the policy proposition based on the engagement responses.

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

No.