

## Engagement Report

### Topic details

<b>Title of policy or policy statement:</b>	Proton Beam Therapy for Breast Cancer (all ages)
<b>Programme of Care:</b>	Cancer
<b>Clinical Reference Group:</b>	Radiotherapy
<b>URN:</b>	1787

### 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.

One respondent (independent provider) was opposed to the policy position. All other respondents were in favour.

The one respondent not in favour suggested patients should be treated with Proton Beam Therapy (PBT). Two other respondents also suggested that sub-groups of patients with breast cancer could be treated with PBT.

The policy working group view is that for all of these patients, there is a lack of evidence supporting the use of PBT in the treatment of patients with breast cancer and that these aspects are best tested in the context of a randomised controlled trial (RCT), which is under development.

No changes have been made to the policy proposition as a result of the feedback received.

### 2. Background

The commissioning recommendation, for this policy proposition, is that PBT is not routinely commissioned for the treatment of breast cancer. This policy proposition has been developed by a Policy Working Group made up of three Consultant Clinical Oncologists (including NHS England National Clinical Lead PBT), two public/patient representatives and one NHS England/Public Health England Public Health Advisor.

### 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 was sent for stakeholder testing for 2 weeks from 28<sup>th</sup> July to 11<sup>th</sup> August 2020. The comments were then 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 questions:

- Do you support the proposition that PBT for breast cancer will not be routinely commissioning based on the evidence review and within the criteria set out in this document?
- Do you believe that there is any additional information that we should have considered in the evidence review? If so, please give brief details.
- Do you believe that there are any potential positive and/or negative impacts on patient care as a result of making this treatment option available? If so, please give details.
- Do you have any further comments on the proposition? If Yes, please describe below, in no more than 500 words, any further comments on the proposed changes to the document as part of this initial 'sense check'.
- Do you support the Equality and Health Inequalities Impact Assessment?
- 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) decided that as the proposition is for not routinely commissioning it was subject to further public consultation. This decision has been assured by the Patient Public Voice Advisory Group.

Consequently, the policy proposition was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 26<sup>th</sup> January 2021 to 25<sup>th</sup> February 2021. Consultation 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:

- Has all the relevant evidence been taken into account?
- Does the impact assessment fairly reflect the likely activity, budget and service impact?
- Does the policy proposition accurately describe the current patient pathway that patients experience?
- Please provide any comments that you may have about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described?
- Are there any changes or additions you think need to be made to this document, and why?

## 4. Engagement Results

### Stakeholder Testing

7 responses were received. 3 were from individuals, 1 from the National Cancer Research Institute (NCRI), 1 from an independent provider, 1 from professional organisation and 1 from a charity/patient organisation.

6 responses agreed with the policy proposition position and 1 was opposed.

A specific telephone conference was held with Breast Cancer Now as advised by the public/patient representatives on the PWG. The purpose of the meeting was to inform Breast Cancer Now of the policy proposition, NHS England intentions regarding conduction trials in this area and provide an update on the trial developments. The proposition and updates were received favourably and supported.

Breast Cancer Now was also asked to advise if any other groups should be contacted and advised that other groups were more active in other areas including prevention and screening and they were the main group focussed on policy and research.

Breast Cancer Now have submitted a stakeholder response.

### Public Consultation

10 responses were received. 1 was for another policy proposition (consultation closed 2018) and was discounted.

Of the 9 remaining responses, 1 was from a patient, 1 from a stakeholder, 4 from clinicians, 1 from NCRI, 1 from a service provider and 1 from an independent provider.

8 responses agreed with the policy proposition and 1 was opposed.

## 5. How has feedback been considered?

### Stakeholder testing

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
<b>Relevant Evidence</b>	
1 respondent recommended that NHS England should consider the evidence for treating subgroups of patients requiring adjuvant radiotherapy for breast cancer (in line with Dutch health authorities).	Dosimetry studies cannot be included in NHS England PBT policy evidence reviews. Whilst it is acknowledged that dosimetry studies show the ability of PBT to reduce dose to the heart compared to standard PBT, the extent to which PBT can reduce an individual patient's cardiac risk remains to be determined as does the acute and medium-term toxicity of PBT compared to standard Radiotherapy.

	NHS England is of the view these aspects are best tested in the context of a Randomised Controlled Trial (RCT). Note: two evidence reviews have been carried out for this proposition as the policy working group had concerns regarding the completeness of the first review.
No other respondents commented on the evidence reviews.	
<b>Impact Assessment</b>	
No comment was made.	Note: There is no impact (financial or activity) on the treatment of patients with breast cancer as this is a not for routine commissioning policy proposition.
<b>Current Patient Pathway</b>	
3 respondents commented that there were groups of patients for which PBT could be used in the treatment of breast cancer. 2 respondents were supportive of the policy position, whilst 1 respondent was not.	NHS England is of the view (and as acknowledged by the respondent) that there is a lack of evidence as to the extent to which PBT can be used with these patients and that these aspects are best tested in the context of a RCT.  Note: The current patient pathway for the treatment of patients with breast cancer remains unchanged as this is a not for routine commissioning policy proposition.
<b>Potential impact on equality and health inequalities</b>	
1 respondent highlighted patients with previous cardiac history (who also may not be able to maintain a Deep inspiration breath hold (DiBH)) and/or requiring internal mammary chain (IMC) irradiation may be being disadvantaged by the policy.  The respondent acknowledged the numbers for this will be very small and there is a lack of evidence to support the use of PBT in this area, but this may negatively impact these patients.	NHS England is of the view (and as acknowledged by the respondent) that there is a lack of evidence as to the extent to which PBT can be used with these patients and that these aspects are best tested in the context of a RCT.
<b>Changes/addition to policy</b>	
1 respondent commented on the phrasing used within the policy proposition and that the proposed clinical trial is not clear in the documentation.	The wording of the proposition has not been amended in order to comply with NHS England process and guidance.

## Public Consultation

Keys themes in feedback	NHS England Response
<b>Relevant Evidence</b>	
<p>1 respondent recommended that NHS England should consider the evidence for treating subgroups of patients requiring adjuvant radiotherapy for breast cancer (in line with Dutch health authorities).</p> <p><b>Note:</b> This was the same response as received during stakeholder consultation.</p>	<p>Dosimetry studies cannot be included in NHS England PBT policy evidence reviews.</p> <p>Whilst it is acknowledged that dosimetry studies show the ability of PBT to reduce dose to the heart compared to standard PBT, the extent to which PBT can reduce an individual patient's cardiac risk remains to be determined as does the acute and medium-term toxicity of PBT compared to standard RT.</p> <p>NHS England is of the view these aspects are best tested in the context of a RCT.</p> <p>Note: two evidence reviews have been carried out for this policy proposition as the policy working group had concerns regarding the completeness of the first review.</p>
<p>No other respondents commented on the evidence reviews.</p>	
<b>Impact Assessment</b>	
<p>No comment was made.</p>	<p>Note: There is no impact (financial or activity) on the treatment of patients with breast cancer as this is a not for routine commissioning policy proposition.</p>
<b>Current Patient Pathway</b>	
<p>No comment was made.</p>	<p>Note: The current patient pathway for the treatment of patients with breast cancer remains unchanged as this is a not for routine commissioning policy proposition.</p>
<b>Potential impact on equality and health inequalities</b>	
<p>3 respondents were supportive of clinical trials in this area.</p> <p>1 respondent stated that patients in more deprived socio-economic groups are more likely to be subject to the risk of cardiac events, but would be expected to benefit from PBT.</p>	<p>NHS England is of the view these aspects are best tested in the context of a RCT.</p>

<b>Changes/addition to policy</b>	
1 respondent commented a definition of the principal aims of proton therapy for patients being treated with adjuvant radiotherapy for breast cancer would make it clear that rather than achieving a better tumour control the principal aim is to minimise long-term cardiac morbidity. In the case of late cardiac events, because of the latent period of several decades, to date it has not been possible to acquire outcome data from RCTs and therefore in advance of RCT outcome data being available it is reasonable to consider data from modelling comparisons, as has been applied to proton therapy for the treatment of children.	NHS England is of the view these aspects are best tested in the context of a RCT.

**6. 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.

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

None.