Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1778		
Policy Title	Hyperbaric Oxygen Therapy for Soft Tissue Radiation Damage in Patients with a History of Pelvic Irradiation for Malignant Disease Proposal **not for routine commission** (ref A3.1)		
Lead Commissioner	Jacquie Kemp	**Clinical Lead**	Mark Glover
Finance Lead	Jazz Nandra	**Analytical Lead**	Click here to enter text.

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About this Impact Assessment: instructions for completion and explanatory notes
• Each section is divided into themes. • Each theme sets out a number of questions. • All questions are answered by selecting a drop down option or including free text. • Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text. • Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided. • Where assumptions are included where data is not available, this is specified.

Section A - Activity Impact	
A1 Current Patient Population & Demography / Growth	
A1.1 Prevalence of the disease/condition.	Late radiation tissue injury affects between 5% and 15% of long time survivors who received radiotherapy with the incidence varying with dose, age and treatment site *Source: Policy Proposition section 6*
A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	N/A do not routinely commission. *Source:* Policy proposition Please specify Click here to enter text.
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**All ages** Please specify Click here to enter text.
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	N/A *Source: required* Please specify Click here to enter text.
A1.5 How is the population currently distributed geographically?	**unknown** If unevenly, estimate regional distribution by %: North: enter %

	<table><tr><td>Midlands & East</td><td>enter %</td></tr><tr><td>London</td><td>enter %</td></tr><tr><td>South</td><td>enter %</td></tr></table> *Source: Policy Proposition section 6* Please specify Click here to enter text.
A2 Future Patient Population & Demography	
A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?	**Constant** If other, Click here to enter text. *Source: Policy Proposition section 6*
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	**No** Please specify Click here to enter text. *Source: Policy Proposition section 6/other*
A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed policy commissioning criteria, per year in years 2-5 and 10? Are these numbers in line with ONS growth assumptions for the age	<table><tr><td>YR2 +/-</td><td>0</td></tr><tr><td>YR3 +/-</td><td>0</td></tr><tr><td>YR4 +/-</td><td>0</td></tr><tr><td>YR5 +/-</td><td>0</td></tr><tr><td>YR10 +/-</td><td>0</td></tr></table>

specific population? If not please justify the growth assumptions made.	**N/A do not commission policy** *Source: Service specification proposition section 3.1* **No** Click here to enter text.
A3 Activity	
A3.1 What is the purpose of new policy?	**Revise existing policy (expand or resrtict an existing treatment threshold / Add an additional line of treatment / stage of treatment** Please specify This policy confirms a do not routinely commission for the use of Hyperbaric Oxygen Therapy for Soft Tissue Radiation Damage in Patients with a History of Pelvic Irradiation for Malignant Disease
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	See A1.1 There is currently some access for this intervention with some HBOT units not taking referrals for this indication. *Source: Capacity and activity returns from providers* Please specify Click here to enter text.
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	*N/A do not routine commission policy proposition* *Source: Policy proposition* Please specify Click here to enter text.
A3.4 What is the estimated annual activity associated with the next	Unknown

best alternative comparator pathway for the eligible population? If the only alternative is the existing pathway, please state 'not applicable' and move to A4.	*Source:* Evidence review Please specify Click here to enter text.
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Most patients would receive symptom management with or without intravesical hyaluronic acid instillation (HA) or argon plasma coagulation (APC).and antibiotics. Additionally there is currently some HBOT access for this intervention with some HBOT units not taking referrals for this indication *Sourc Current policy and new policy proposition*
A4.2. What are the current treatment access and stopping criteria?	N/A. *Source: policy proposition*
A4.3 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, please specify Not known as not routinely commissioned a) 0% b) 0% c) 0% d) 0% e) 0% *Source: Evidence review*
A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)	

A5.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	**<u>Yes</u>** If yes, Patients will receive symptom management with or without intravesical hyaluronic acid instillation (HA) or argon plasma coagulation (APC).and management of underlying cause. There is little published data available. *Source: ER*
A5.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	Total estimated eligible N/A as do not routinely commission policy a) enter % b) enter % c) enter % d) enter % e) enter % *Source: required*
A6 New Patient Pathway	
A6.1 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	If not known, please specify N/A a) 0% b) 0% c) 0% d) 0% e) 0% *Source: Current published policy and revised policy proposition*

A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**<u>Time limited</u>** For time limited treatments, specify frequency and/or duration. N/A *Source:* N/A do not routinely commission
A7 Treatment Setting	
A7.1 How is this treatment delivered to the patient?	*Select all that apply:* Emergency/Urgent care attendance ☐ Acute Trust: inpatient ☒ Acute Trust: day patient ☐ Acute Trust: outpatient ☐ Mental Health provider: inpatient ☐ Mental Health provider: outpatient ☐ Community setting ☐ Homecare ☐ Other ☒ Please specify:
A7.2 What is the current number of contracted providers for the eligible population by region?	NORTH: 2 MIDLANDS & EAST: 2 LONDON: 2

	SOUTH: 4
A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**Not yet known** Please specify: Any change will be subject to the outcome of the service review and subsequent procurement *Source:* *Commissioning plan*
A8 Coding	
A8.1 Specify the datasets used to record the new patient pathway activity. *expected to be populated for all commissioned activity	**Not applicable**:

Aggregate Contract Monitoring *	☐
Patient level contract monitoring	☐
Patient level drugs dataset	☐
Patient level devices dataset	☐
Devices supply chain reconciliation dataset	☐
Secondary Usage Service (SUS+)	☐
Mental Health Services DataSet (MHSDS)	☐
National Return**	☐
Clinical Database**	☐
Other**	☐

**If National Return, Clinical database or other selected, please specify:

<table>
<tr><td></td><td>International registry hosted in England by ArdenGem</td></tr>
<tr><td>A8.2 Specify how the activity related to the new patient pathway will be identified.</td><td><u>Not applicable</u>

<table><tr><td>OPCS v4.8</td><td>☐</td></tr><tr><td>ICD10</td><td>☐</td></tr><tr><td>Treatment function code</td><td>☐</td></tr><tr><td>Main Speciality code</td><td>☐</td></tr><tr><td>HRG</td><td>☐</td></tr><tr><td>SNOMED</td><td>☐</td></tr><tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☐</td></tr></table></td></tr>
<tr><td>A8.3 Identification Rules for Drugs:
How are drug costs captured?</td><td><u>Not applicable</u>
If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication:
Click here to enter text.
If the drug has NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead:
Click here to enter text.</td></tr>
<tr><td>A8.4 Identification Rules for Devices:
How are device costs captured?</td><td><u>Not applicable</u>
If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance).
Click here to enter text.</td></tr>
</table>

	If the device is not excluded from Tariff **nor** covered within existing National or Local prices please specify details of action required and confirm that this has been discussed with the HCTED team. Click here to enter text.
A8.5 **Identification Rules for Activity:** How are activity costs captured?	**Not captured by an existing specialised service line** If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy). Click here to enter text. If activity costs are already captured please specify whether this service needs a separate code. Choose an item. If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team. Click here to enter text. If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. **No**
A9 Monitoring	
A9.1 **Contracts** Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.	**None** Please specify International registry to be completed by all providers
A9.2 **Excluded Drugs and Devices (not covered by the Zero Cost Model)** For treatments which are tariff excluded drugs or devices not	*Select all that apply:* Drugs or Device MDS ☐

covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval systems.	<table><tr><td>Blueteq</td><td>☐</td></tr><tr><td>Other prior approval</td><td>☐</td></tr></table> Please specify: Click here to enter text.
A9.3 **Business intelligence** Is there potential for duplicate reporting?	**No** If yes, please specify mitigation: Click here to enter text.
A9.4 **Contract monitoring** Is this part of routine contract monitoring?	**No** If yes, please specify contract monitoring requirement: Click here to enter text.
A9.5 **Dashboard reporting** Specify whether a dashboard exists for the proposed intervention?	**No not for this indication as not routine commission proposal** If no, will one be developed? Click here to enter text.
A9.6 **NICE reporting** Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	**Yes** If yes, specify how performance monitoring data will be used for this purpose. Part of dashboard requirements
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Click here to enter text. *Source: required*

<table>
<tr><td>B1.2 Will the proposition change the way the commissioned service is organised?</td><td><u>The proposition will not change this however there is a service review that will result in a national procurement which may reduce the number of centres delivering this service</u>
Please specify:
Click here to enter text.
Source: Service review gateway documents</td></tr>
<tr><td>B1.3 Will the proposition require a new approach to the organisation of care?</td><td><u>As detailed in B1.2</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td colspan="2">B2 Geography & Access</td></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td>N/A
Select all that apply:<table><tr><td>GP</td><td>☒</td></tr><tr><td>Secondary care</td><td>☒</td></tr><tr><td>Tertiary care</td><td>☐</td></tr><tr><td>Other</td><td>☐</td></tr></table></td></tr>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>Decrease</u>
Please specify:
HBOT for is not currently commissioned for this indication, however there has been some limited access for patients, this policy changes that position and consequently patients will no longer have access to this treatment.</td></tr>
</table>

B2.3 Is the new policy likely to improve equity of access?	**Decrease** Please specify: Click here to enter text. *Source: Equalities Impact Assessment*
B2.4 Is the new policy likely to improve equality of access and/or outcomes?	**Decrease** Please specify: Click here to enter text. *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**Procurement action** Please specify: Procurement as part of the outcome of the associated service review anticipated to commence early 2018.
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**Yes - go to B3.3** If yes, specify the likely time to implementation: The updated policy will be published at the same time as the outcome and timelines for procurement are released.
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	**Yes** If yes, outline the plan: Current services will continue to provide care until the completion of the national procurement. There will be no changes to either activity or contracts until notice of change has been released after completion and award of the procurement exercise.

<table>
<tr><td>B3.4 Is a change in provider physical infrastructure required?</td><td><u>No</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.5 Is a change in provider staffing required?</td><td><u>No</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</td><td><u>No</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td><u>No</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</td><td><u>No</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region</td><td>Choose an item.
Please complete table:
<table>
<tr><td>Region</td><td>Current no. of providers</td><td>Future
State expected range</td><td>Provisional or confirmed</td></tr>
<tr><td>North</td><td>2</td><td>2</td><td><u>P</u></td></tr>
<tr><td>Midlands &</td><td>2</td><td>2</td><td><u>P</u></td></tr>
</table>
</td></tr>
</table>

	East | | | London | 2 | 1 | P South | 4 | 3 | P Total | 10 | 8 | P Please specify: Pending outcome of procurement
B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.	*Select all that apply:* Publication and notification of new policy ☐ Market intervention required ☐ Competitive selection process to secure increase or decrease provider configuration ☒ Price-based selection process to maximise cost effectiveness ☒ Any qualified provider ☒ National Commercial Agreements e.g. drugs, devices ☐ Procurement ☒ Other ☒ Please specify: Click here to enter text.
B4 Place-based Commissioning	
B4.1 Is this service currently subject to, or planned for, place-based	**No**

commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	Please specify: Click here to enter text.

Section C - Finance Impact

C1 Tariff/Pricing

C1.1 How is the service contracted and/or charged?
Only specify for the relevant section of the patient pathway

Select all that apply:

Drugs	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff – pass through	☐
	Excluded from tariff - other	☐
Devices	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff (excluding ZCM) – pass through	☐
	Excluded from tariff (excluding ZCM) – other	☐
	Via Zero Cost Model	☐
Activity	Paid entirely by National Tariffs	☐
	Paid entirely by Local Tariffs	☒
	Partially paid by National Tariffs	☐
	Partially paid by Local Tariffs	☐
	Part/fully paid under a Block arrangement	☒
	Part/fully paid under Pass-Through arrangements	☐
	Part/fully paid under Other arrangements	☒

C1.2 **Drug Costs** Where not included in national or local tariffs, list each drug or combination, dosage, quantity, **list** price including VAT if applicable and any other key information e.g. Chemotherapy Regime. NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	N/A
C1.3 **Device Costs** Where not included in national or local tariff, list each element of the excluded device, quantity, **list or expected** price including VAT if applicable and any other key information. NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	N/A
C1.4 **Activity Costs covered by National Tariffs** List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	N/A
C1.5 **Activity Costs covered by Local Tariff** List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.	N/A
C1.6 **Other Activity Costs not covered by National or Local Tariff** Include descriptions and estimates of all key costs.	The current spend/budget for HBOT services (England) is £8.8m There are various models across the country with variation in costs. This will be addressed within the current budget during the service review procurement.
C1.7 Are there any prior approval mechanisms required either	**No**

<table>
<tr><td>during implementation or permanently?</td><td>Please specify: Click here to enter text.</td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
<tr><td>C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?

Are there any changes expected in year 6-10 which would impact the model?</td><td><table><tr><td>YR1</td><td>N/A</td></tr><tr><td>YR2</td><td>N/A</td></tr><tr><td>YR3</td><td>N/A</td></tr><tr><td>YR4</td><td>N/A</td></tr><tr><td>YR5</td><td>N/A</td></tr></table>If yes, please specify:
Click here to enter text.</td></tr>
<tr><td colspan="2">C3 Overall Cost Impact of this Policy to NHS England</td></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.</td><td><u>Cost neutral</u>
Please specify:
The current budget will be used to provide reduced number of centres providing 24/7 access for emergency treatment.</td></tr>
<tr><td>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</td><td>Whilst the proposal is anticipated to be cost neutral, the procurement may result in some savings but this is currently unknown.</td></tr>
<tr><td>C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?</td><td>N/A</td></tr>
</table>

C4 Overall cost impact of this policy to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **No impact on CCGs** Budget impact for providers: **No impact on providers** Please specify: Click here to enter text.
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost neutral** Please specify: Click here to enter text.
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Click here to enter text.
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No** Please specify: Click here to enter text.
C5 Funding	
C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	N/A

C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	No risk if this is published alongside the outcome of the procurement and associated contract awards.
C6.2 How can these risks be mitigated?	Click here to enter text.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Click here to enter text.
C6.4 What scenario has been approved and why?	Click here to enter text.
C7 Value for Money	
C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?	**There is no published evidence of cost-effectiveness** Please specify: Click here to enter text.
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	*Select all that apply:* Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment ☐ Available pricing data suggests the treatment is lower cost compared to current/comparator treatment ☐ Available clinical practice data suggests the new treatment has the potential to improve value for money ☐

	Other data has been identified ☐ No data has been identified ☐ The data supports a high level of certainty about the impact on value ☐ The data does not support a high level of certainty about the impact on value ☒ Please specify: Click here to enter text.
C8 Cost Profile	
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**No** If yes, specify type and range: Click here to enter text.
C8.2 If yes, confirm the source of funds to meet these costs.	Click here to enter text.