# Integrated Impact Assessment Report for Clinical Commissioning Policies

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| **Policy Reference Number** | 1631 | | |
| **Policy Title** | Hypofractionated external beam radiotherapy in the treatment of localised prostate cancer. | | |
| **Lead Commissioner** | Kim Fell | **Clinical Lead** | Professor D Dearnaley |
| **Finance Lead** | Jacqui Lowe | **Analytical Lead** | Jacqui Low |

| **Integrated Impact Assessment – Index** | | |
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| Sections A – C | |
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| **Theme / Questions:**<br>Each section is divided into themes.<br>Each theme sets out a number of questions. | **Responses / Comments:**<br>All questions are answered by selecting a drop down option or including free text in line with the specified word limit.<br>Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided.<br>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. | 41,736 new cases of prostate cancer were diagnosed in the UK in 2011.<br><br>*Source: Policy Proposition section 6*<br>(Cancer Research UK, 2017) |
| A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria. | Approximately 9,000 patients per year.<br><br>*Source:* Policy Proposition, section 6 (Radiotherapy Dataset) |
| A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria. | **Adults** |
| A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria | Prostate cancer is particularly common among older men; two-thirds of those who die from prostate cancer are over the age of 75 years.<br><br>*Source:* (Cancer Research UK, 2017) |

<table>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>Evenly</u><br><br>Source: Policy Proposition section 6</td></tr>
<tr><td colspan="2">A2 Future Patient Population & Demography</td></tr>
<tr><td>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?</td><td><u>Increasing</u><br><br>Incidence of prostate cancer has risen by 44% since the 1970s and is characterised by a steep acceleration in the 1990’s. Incidence is thought to have grown by around 6% during the course of the last decade.<br><br>Source: Cancer Statistics, Cancer Research UK, 2017</td></tr>
<tr><td>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</td><td><u>Not known</u><br><br>Source:</td></tr>
<tr><td>A2.3 Expected net increase or decrease in the number of patients who will be eligible for treatment, according to the proposed policy commissioning criteria, per year in years 2-5 and 10?</td><td><table><tr><td>YR2 +/-</td><td>9,364</td></tr><tr><td>YR3 +/-</td><td>9,551</td></tr><tr><td>YR4 +/-</td><td>9,742</td></tr><tr><td>YR5 +/-</td><td>9,937</td></tr><tr><td>YR10 +/-</td><td>10, 972</td></tr></table><br>Activity increases have been modelled in-line with forecast growth in cancer incidence rates, this is estimated at 2% per year.<br><br>Source: Policy Working Group</td></tr>
</table>

| **A3 Activity** | |
|---|---|
| A3.1 What is the purpose of new policy? | **<u>Remove and replace a currently routinely commissioned treatment</u>** |
| A3.2 What is the annual activity associated with the existing pathway for the eligible population? | 9000 episodes of treatment per year using conventional external beam radiotherapy defined as 2Gy per day up to a usual dose of at least 74 Gy in 37 daily treatments over 7 ½ weeks.<br><br>*Source:* Policy Proposition, section 6 (Radiotherapy Dataset) |
| A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population? | 9000 episodes per year of hypo-fractionated external beam radiotherapy for the treatment of localised prostate cancer uses larger than conventional fraction sizes (more than 2 Gy) usually delivered over a shorter overall treatment time, in 20 daily treatments.<br><br>*Source:* Policy Proposition, section 6 (Radiotherapy Dataset) |
| A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? | 9000 episodes of treatment per year using conventional external beam radiotherapy defined as 2Gy per day up to a usual dose of at least 74 Gy in 37 daily treatments over 7 ½ weeks.<br><br>*Source:* Policy Proposition, section 6 (Radiotherapy Dataset) |
| **A4 Existing Patient Pathway** | |

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| A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned:<br>• Treatment or intervention<br>• Patient pathway<br>• Eligibility and/or uptake estimates. | External beam radiotherapy is widely used to treat prostate cancer. Management options include external beam radiotherapy, brachytherapy, radical prostatectomy, active surveillance (for men with low-risk disease) and watchful waiting (for those unsuitable for radical curative treatment) External-beam radiotherapy is most appropriate for men with intermediate or high risk disease.<br><br>*Source: National Comprehensive Cancer Network, 2011* |
| A4.2. What are the current treatment access and stopping criteria? | Not applicable. |
| A4.3 What percentage of the total eligible population is expected to:<br>a) Be clinically assessed for treatment<br>b) Be considered to meet an exclusion criteria following assessment<br>c) Choose to initiate treatment<br>d) Comply with treatment<br>e) Complete treatment? | a) 100%<br>b) 100%<br><br>c) 100%<br>d) 100%<br>e) 100%<br><br>*Source: Radiotherapy Dataset, 2015* |
| **A5 Comparator (next best alternative treatment) Patient Pathway** | |
| A5.1 **Next best comparator**:<br>Is there another 'next best' alternative treatment which is a relevant comparator?<br>*If yes, describe relevant*<br>• *Treatment or intervention*<br>• *Patient pathway*<br>• *Actual or estimated eligibility and uptake* | **<u>Yes - additional comparator routinely commissioned</u>**<br><br>The 'next best' alternative routinely commissioned treatment is conventional radiotherapy<br><br>*Source: Policy Working Group* |

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|---|---|
| A5.2 What percentage of the total eligible population is estimated to:<br>a) Be clinically assessed for treatment<br>b) Be considered to meet an exclusion criteria following assessment<br>c) Choose to initiate treatment<br>d) Comply with treatment<br>e) Complete treatment? | Total estimated eligible<br><br>a) 100%<br>b) 100%<br><br>c) 100%<br>d) 100%<br>e) 100% |
| **A6 New Patient Pathway** | |
| A6.1 What percentage of the total eligible population is expected to:<br>a) Be clinically assessed for treatment<br>b) Be considered to meet an exclusion criteria following assessment<br>c) Choose to initiate treatment<br>d) Comply with treatment<br>e) Complete treatment? | <br><br>a) 100%<br>b) 30%<br><br>c) 70%<br>d) 70%<br>e) 70% |
| A6.2 Specify the nature and duration of the proposed new treatment or intervention. | **<u>One off</u>**<br><br>Hypo-fractionated external beam radiotherapy for the treatment of localised prostate cancer uses larger than conventional fraction sizes (more than 2 Gy) usually delivered over a shorter overall treatment time, for example, 60Gy in 20 daily fractions of 3 Gy over 4 weeks. Conventionally fractionated radiotherapy is defined as 2Gy per day up to a usual dose of at least 74 Gy in 37 daily fractions over 7 ½ weeks.<br><br>*Source: Policy Proposition* |
| **A7 Treatment Setting** | |

<table>
<tr><td>A7.1 How is this treatment delivered to the patient?</td><td><u>Acute Trust: outpatient</u></td></tr>
<tr><td>A7.2 What is the current number of contracted providers for the eligible population by region?</td><td><table>
<tr><td>NORTH</td><td>9</td></tr>
<tr><td>MIDLANDS & EAST</td><td>17</td></tr>
<tr><td>LONDON</td><td>8</td></tr>
<tr><td>SOUTH</td><td>17</td></tr>
</table></td></tr>
<tr><td>A7.3 Does the proposition require a change of delivery setting or capacity requirements?</td><td><u>No</u></td></tr>
<tr><td colspan="2">A8 Coding</td></tr>
<tr><td>A8.1 Specify the datasets used to record the new patient pathway activity.<br><br>*expected to be populated for all commissioned activity</td><td>Select all that apply:<table>
<tr><td>Aggregate Contract Monitoring *</td><td>☐</td></tr>
<tr><td>Patient level contract monitoring</td><td>☐</td></tr>
<tr><td>Patient level drugs dataset</td><td>☐</td></tr>
<tr><td>Patient level devices dataset</td><td>☐</td></tr>
<tr><td>Devices supply chain reconciliation dataset</td><td>☐</td></tr>
<tr><td>Secondary Usage Service (SUS+)</td><td>☒</td></tr>
<tr><td>Mental Health Services DataSet (MHSDS)</td><td>☐</td></tr>
<tr><td>National Return**</td><td>☐</td></tr>
<tr><td>Clinical Database**</td><td>☐</td></tr>
<tr><td>Other**</td><td>☒</td></tr>
</table><br>**If National Return, Clinical database or other selected, list</td></tr>
</table>

<table>
<tr><td></td><td>here: Radiotherapy Dataset</td></tr>
<tr><td>A8.2 Specify how the activity related to the new patient pathway will be identified.</td><td>Select all that apply:<br><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><br>Describe a suitable Identification Rule for the service or procedure:<br>Radiotherapy Dataset</td></tr>
<tr><td>A8.3 Does the service require the creation of a new specialised service line?</td><td><u>No</u></td></tr>
</table>

| **A9 Monitoring** | |
|---|---|
| A9.1 **Contracts**<br>Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule. | **None** |
| A9.2 **Excluded Drugs**<br>For treatments which are tariff excluded drugs, specify the pharmacy monitoring required, for example reporting or use of prior approval systems. | Not applicable. |
| A9.3 **Business intelligence**<br>Specify analytical information, monitoring and reporting requirements, including validation requirements, to ensure activity is not double charged through existing routes. | Radiotherapy providers must submit their activity to the national Radiotherapy Dataset (RTDS) on a monthly basis. For reporting purposes, it is expected that 70% of prostate cancer patients requiring radical external beam radiotherapy should receive hypofractionated radiotherapy (i.e., 20 fractions of treatment). |
| A9.4 **Contract monitoring**<br>Specify contract monitoring to be undertaken by supplier managers, and any changes from current arrangements. | Reasons for exceeding 20 fractions in the eligible patient population (i.e., 70%) must be recorded by the Trust and be shown to be appropriate for the treated case-mix. Providers should be aware that NHS England will audit variation in the rates of treatment courses exceeding 20 fractions using RTDS data |
| A9.5 **Dashboard reporting**<br>Specify whether a dashboard exists for the proposed intervention? | **No**<br><br>If no, will one be developed?<br>Yes as an indicator as part of the new Radiotherapy service specification |
| A9.6 **NICE reporting**<br>Are there any directly applicable NICE or | **No** |

<table>
<tr><td>equivalent quality standards which need to be monitored in association with the new policy?</td><td></td></tr>
<tr><td colspan="2">Section B - Service Impact</td></tr>
<tr><td colspan="2">B1 Service Organisation</td></tr>
<tr><td>B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc)</td><td>External beam radiotherapy is currently delivered by 52 providers in England. Prostate is a common cancer and as such will be treated at each of the 52 centres. A service model has been developed which requires that that the treatment of the common cancers continues to be delivered by all providers.<br><br>Source: Policy Proposition</td></tr>
<tr><td>B1.2 Will the proposition change the way the commissioned service is organised?</td><td><u>No</u></td></tr>
<tr><td>B1.3 Will the proposition require a new approach to the organisation of care?</td><td><u>Not applicable.</u></td></tr>
<tr><td colspan="2">B2 Geography & Access</td></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td>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>No impact</u></td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>No impact</u><br><br>Source: Equalities Impact Assessment</td></tr>
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| B2.4 Is the new policy likely to improve equality of access and/or outcomes? | **Increase**<br><br>*Source: Equalities Impact Assessment* |
| **B3 Implementation** | |
| B3.1 Will commissioning or provider action be required before implementation of the proposition can occur? | **No action required** |
| B3.2 **Time to implementation:**<br>Is a lead-in time required prior to implementation? | **No - go to B3.4** |
| B3.3 **Time to implementation:**<br>If lead-in time is required prior to implementation, will an interim plan for implementation be required? | **Not applicable.** |
| B3.4 Is a change in provider physical infrastructure required? | **No** |
| B3.5 Is a change in provider staffing required? | **No** |
| B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place? | **No** |
| B3.7 Are there changes in the support services that need to be in place? | **No** |
| B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor) | **No** |
| 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 | **No change** |

<table>
<tr><td>providers required in each region.</td><td></td></tr>
<tr><td>B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.</td><td>Select all that apply:<table><tr><td>Publication and notification of new policy</td><td>☒</td></tr><tr><td>Market intervention required</td><td>☐</td></tr><tr><td>Competitive selection process to secure increase or decrease provider configuration</td><td>☐</td></tr><tr><td>Price-based selection process to maximise cost effectiveness</td><td>☐</td></tr><tr><td>Any qualified provider</td><td>☐</td></tr><tr><td>National Commercial Agreements e.g. drugs, devices</td><td>☐</td></tr><tr><td>Procurement</td><td>☐</td></tr><tr><td>Other</td><td>☐</td></tr></table></td></tr>
<tr><td colspan="2">B4 Place-based Commissioning</td></tr>
<tr><td>B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)</td><td><u>No</u></td></tr>
<tr><td colspan="2">Section C - Finance Impact</td></tr>
<tr><td colspan="2">C1 Tariff/Pricing</td></tr>
<tr><td>C1.1 Is this treatment paid under national prices?</td><td><u>Yes</u><br><br>Standard Radiotherapy :SC23Z (75.7%) / SC31Z (24.3%) x 37 fractions<br><br>Hypofractionated Radiotherapy: SC31Z x</td></tr>
</table>

<table>
<tr><td></td><td>20 fractions</td></tr>
<tr><td>C1.2 Is this treatment excluded from national prices?</td><td><u>No</u></td></tr>
<tr><td>C1.3 Is this covered under a local price arrangement?<br><br>NB: Local pricing may be subject to commercial confidentiality and must not be disclosed.</td><td><u>No</u></td></tr>
<tr><td>C1.4 Is a new price proposed?</td><td><u>No</u></td></tr>
<tr><td>C1.5 If VAT is payable, is it included in the proposed price?</td><td><u>Not payable</u></td></tr>
<tr><td>C1.6 Will a prior approval mechanism be used to support implementation of the new policy that will require provider compliance to secure reimbursement?</td><td><u>No</u></td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
<tr><td>C2.1 What is the estimated net cost per patient to NHS England, in years 1-5, including follow-up where required?<br><br>NB: Net cost takes account of the impact of the new proposal compared to the existing pathway and any comparators.<br>A4 sets out the existing pathway.<br>A5 sets out any relevant comparator pathway.<br>A6.2 sets out the nature of the proposed treatment (one off / ongoing etc).<br>Inputs summary sets out key input assumptions.</td><td>
<table>
<tr><td>YR1</td><td>-£582</td></tr>
<tr><td>YR2</td><td>-£582</td></tr>
<tr><td>YR3</td><td>-£582</td></tr>
<tr><td>YR4</td><td>-£582</td></tr>
<tr><td>YR5</td><td>-£582</td></tr>
</table>
<br>Cost of Standard Radiotherapy Fractions (37) = £4,590+MFF<br>Cost of Hypofractionated Radiotherapy = £2,920+MFF<br>Saving = £1,670+MFF<br><br>Assumption: 30% of patients continue to receive standard treatment; 37.7% of patients are already receiving hypofractionated
</td></tr>
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| | radiotherapy; 32.3% of patients transfer to hypofractionated radiotherapy.<br><br>MFF is an average of 7.95% |
| **C3 Overall Cost Impact of this Policy to NHS England** | |
| C3.1 Specify the budget impact of the proposal on NHS England. | **Cost saving**<br>Commissioner savings of £5.3m in year 1 rising to £5.8m in year 5. |
| C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured. | **Not applicable**. |
| 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 agreed, and calculated? | **Not applicable.** |
| C3.4 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, are CCGs aware of the values to be transferred? | **Not applicable.** |
| **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:<br>**Cost neutral**<br>Budget impact for providers:<br>**Cost neutral**<br>Whilst there is a reduction in the number of fractions, in reality the cost of providing a radiotherapy service is unlikely to change as (i) reduced activity will be used to meet existing capacity issues and (ii) the average cost of fractions is increasing (due to the higher proportion of IMRT). |

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| C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole. | **Cost saving** |
| C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured | **Not applicable**. |
| C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders? | **No** |
| **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. | **Not applicable**. |
| **C6 Financial Risks Associated with Implementing this Policy** | |
| C6.1 What are the material financial risks to implementing this policy? | There are no significant financial risks. Robust financial modelling based on data provided by providers has been undertaken. |
| C6.2 How can these risks be mitigated? | Not applicable. |
| C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios? | Not applicable. |
| C6.4 What scenario has been approved and why? | Not applicable. |
| **C7 Value for Money** | |
| C7.1 What evidence is available that the treatment is cost effective? | **Published evidence of cost** |

<table>
<tr><td>C7.2 What issues or risks are associated with this assessment? e.g. quality or availability of evidence</td><td>Select all that apply:<table><tr><td>Some uncertainty about number of eligible patients</td><td>☒</td></tr><tr><td>Some uncertainty about estimates of uptake</td><td>☐</td></tr><tr><td>Some uncertainty about future drug prices</td><td>☐</td></tr><tr><td>Potential for legal challenge</td><td>☐</td></tr></table></td></tr>
<tr><td colspan="2">C8 Cost Profile</td></tr>
<tr><td>C8.1 Are there non-recurrent capital or revenue costs associated with this policy?</td><td><u>No</u></td></tr>
<tr><td>C8.2 If yes, confirm the source of funds to meet these costs.</td><td>Not applicable.</td></tr>
</table>

**SUMMARY: INPUTS (BASED ON POLICY PROPOSITION AND IMPACT ASSESSMENT) TO BE USED FOR CALCULATION OF COST PER PATIENT AND BUDGET IMPACT**

| **INPUT ASSUMPTIONS** | **Yr 1** | **Yr2** | **Yr 3** | **Yr 4** | **Yr5** |
|---|---|---|---|---|---|
| 1. Patients eligible | 9,180 | 9,364 | 9,551 | 9,742 | 9,937 |
| 2. Uptake | 70% | 70% | 70% | 70% | 70% |
| 3. Treatment duration | 4 weeks | | | | |
| 4. Treatment regimen factors (dosing, discontinuation etc) | Treatment would be delivered in 20 daily fractions of 3 Gy over 4 weeks (total of 60 Gy). | | | | |
| 5. Treatment effectiveness | Not applicable. | | | | |
| 6. Number needed to treat to achieve primary outcome (from published evidence) | Assumed that this treatment will be suitable for approximately 70% of patients. | | | | |
| 7. Treatment price (list price used where commercially confidential discounts available) | **Cost per patient = £3,774**<br><br>Total number of fractions delivered = 230, 418<br><br>Total cost ('000s) = £31,404.80 | **Cost per patient = £3,774**<br><br>Total number of fractions delivered = 235, 036<br><br>Total cost ('000s) = £32,034.2 | **Cost per patient = £3,774**<br><br>Total number of fractions delivered = 239, 730<br><br>Total cost ('000s) = £32,674 | **Cost per patient = £3,774**<br><br>Total number of fractions delivered = 244, 524<br><br>Total cost ('000s) = £33,227.4 | **Cost per patient = £3,774**<br><br>Total number of fractions delivered = 249, 419<br><br>Total cost ('000s) = £33, 994.5 |
| | Based on assumption treatment would be delivered in 20 daily fractions of 3Gy over 4 weeks. | | | | |
| 8. Care cost associated with proposal (tariff price or range used where commercially confidential prices in place) | Not applicable. | | | | |
| 9. Costs of existing or alternative pathway which the proposal will offset (deaths / morbidity / healthcare | Conventional radiotherapy.<br><br>Total number of fractions delivered = 280, 671 | Conventional radiotherapy.<br><br>Total number of fractions delivered = 286, 389 | Conventional radiotherapy.<br><br>Total number of fractions delivered = 292, 108 | Conventional radiotherapy.<br><br>Total number of fractions delivered = 297, 950 | Conventional radiotherapy.<br><br>Total number of fractions delivered = 303, 913 |

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| | utilisation avoided, other treatments reduced or avoided)) | Total cost (‘000s) = £36,350.2 | Total cost (‘000s) = £37,078.9 | Total cost (‘000s) = £37,819.3 | Total cost (‘000s) = £38,575.7 | Total cost (‘000s) = £39,347.7 |