

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B01X04		
Policy Title	Radiotherapy after primary surgery for I	preast cancer	
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	Section K - Activi	ty Impact	
Theme	Questions	Comments (Include source made and any issues with	e of information and details of assumptions the data)
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?		to routinely commission a 15-fraction er primary surgery for breast cancer. ⁱ
			ation of those with breast cancer in bund 80:10,000 or c. 430,000. ⁱⁱ
		cases for every 100,000 fe	gest that there are 155 new breast cancer males in the UK and 1 for every 100,000 nce is estimated at c. 44,000. ⁱⁱⁱ

K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	K1.2 Adjuvant therapy after primary surgery for breast cancer is considered for patients with early invasive breast cancer. ^{iv} The policy applies to patients who receive external beam radiotherapy
	(EBRT) as part of their treatment. In 2014/15, the number of patients with breast cancer who received EBRT as part of their treatment is estimated at c. 31,200, ^v or around 71% of the incident population. For these patients, the policy sets the standard fraction schedule at 15.
	Of these patients, an estimated 88% (c. 27,500 patients) would be eligible to receive 15 fractions based on current data. ^{vi}
K1.3 What age group is the treatment indicated for?	K1.3 This treatment is indicated for all ages.
K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 Patients are most frequently diagnosed with breast cancer between the ages of 45 and 70. ^{vii} Typically, the patients taking up this treatment are thus expected to fall in this age range.
K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 As described in K1.2, in 2014/15, there are an estimated 27,500 patients (or 88% of cases of EBRT) receiving 15 fractions of radiotherapy as part of their treatment.
	Around 3,700 patients are estimated to be receiving more than the standard schedule of 15 fractions, at an average of c.24 each.viii

	The total number of fractions delivered is estimated at c.500,000.
K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	 K1.6 As set out in K1.2, EBRT is an adjuvant therapy after primary surgery for breast cancer and is not an ongoing treatment.^{ix} Prevalence is assumed to grow in line with demographic growth and future prevalence is estimated to be in the region of:^x ~ 435,000 in 2016/17 ~ 438,000 in 2017/18 ~ 445,000 in 2020/21 Future incidence is estimated in the region of:^{xi} ~ 44,700 in 2016/17 ~ 45,000 in 2017/18 ~ 46,000 in 2020/21
K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years	 K1.7 In view of the continuous evolution of the treatment of breast cancer, no specific growth rate for radiotherapy activity could be determined. ^{xii} Demographic growth has therefore been applied to current activity a described in K1.5. Future activity is estimated in the region of:^{xiii} <i>Patients receiving 15 fractions:</i> ~ 27,900 (or ~ 418k fractions in total) in 2016/17 ~ 28,600 (or ~ 421k fractions in total) in 2017/18 ~ 28,600 (or ~ 430k fractions in total) in 2020/21 <i>Patients receiving more than 15 fractions (c.24 on average):</i> ~ 3,800 (or ~ 91k fractions in total) in 2016/17

		 ~ 3,900 (or ~ 94k fractions in total) in 2020/21
	K1.8 How is the population currently distributed geographically?	K1.8 Across England, some geographic variation in prevalence was identified. Age standardised prevalence rates for breast cancer are significantly higher in Dorset and South East London, which both have 10 year prevalence rates at over 450 per 100,000 against the national average of around 420. ^{xiv}
K2 Future Patient Population & Demography	K2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	K2.1 Radiotherapy following surgery for patients with breast cancer is already routinely commissioned. This policy is consistent with the existing policy statement (B01/PS/d), as published in 2015, which recommends a standard fraction schedule of 15 fractions. ^{xv}
	K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival)	K2.2 Lifestyle factors such as obesity, alcohol intake etc. could increase the risk of breast cancer. ^{xvi} However, changes in screening and future identification of biological subgroups could the prevalence of the population that requires treatment. ^{xvii}
	K 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details	K2.3 No evidence suggesting significant changes in the geographical or demographic distribution was identified.
	K2.4 What is the resulting expected net	K2.4. The change in the number of patients receiving a 15 fraction

	increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?	schedule under this policy is expected to be nil. This is because since the policy statement has been in place, 88% of the patients are already receiving the recommended standard fractionation schedule (compared to the initially recommended limit of <i>at least</i> 80%). ^{xviii}
K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet	K3.1 As described in K1.5, there are an estimated 27,500 patients (or 88% of cases of EBRT) receiving 15 fractions of radiotherapy as part of their treatment. An estimated 3,700 patients are receiving more than the standard schedule of 15 fractions, at an average of c.24 each.
	K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet	 K3.2 Under the policy, the number of patients receiving 15 fractions could remain at 88% of those having radiotherapy.^{xix} <i>Patients receiving 15 fractions:</i> ~ 27,900 (or ~ 418k fractions in total) in 2016/17 ~ 28,100 (or ~ 421k fractions in total) in 2017/18 ~ 28,600 (or ~ 430k fractions in total) in 2020/21 <i>Patients receiving more than 15 fractions (c.24 on average):</i> ~ 3,800 (or ~ 91k fractions in total) in 2016/17 ~ 3,800 (or ~ 92k fractions in total) in 2017/18 ~ 3,900 (or ~ 94k fractions in total) in 2020/21
	K3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not	K3.3 As described in K1.7, future activity in the do nothing scenario is estimated in the region of:

	adopted? Please details in accompanying excel sheet	Patients receiving 15 fractions: $\sim 27,900$ (or $\sim 418k$ fractions in total) in 2016/17 $\sim 28,100$ (or $\sim 421k$ fractions in total) in 2017/18 $\sim 28,600$ (or $\sim 430k$ fractions in total) in 2020/21Patients receiving more than 15 fractions (c.24 on average): $\sim 3,800$ (or $\sim 91k$ fractions in total) in 2016/17 $\sim 3,800$ (or $\sim 92k$ fractions in total) in 2017/18 $\sim 3,900$ (or $\sim 94k$ fractions in total) in 2020/21
K4 Existing Patient Pathway	K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity	K4.1 Radiotherapy is currently routinely commissioned following primary breast cancer surgery, as part of an overall cancer management and treatment pathway. The service specifications for radiotherapy (B01/S/a) describe the detail of the care pathways for this service. Decisions on the overall treatment plan relate back to an MDT discussion and decision. If EBRT is indicated, the patient is referred to a clinical oncologist for assessment, treatment planning and delivery of radiation fractions. Each fraction of radiation is delivered on one visit, usually on an outpatient basis.
	K4.2. What are the current treatment access criteria?	K4.2 Access is determined by MDT assessment following surgery for breast cancer.
	K4.3 What are the current treatment stopping points?	K4.3 Stopping points are determined by MDT assessment.

K5 Comparator (next best alternative treatment) Patient Pathway	K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity.	K5.1 The proposed fractionation schedule of 40Gy in 15 fractions is already routinely commissioned through a policy statement.
	K5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	K5.2 Not applicable.
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy	K6.1 The new policy specifies the number of fractions of radiotherapy to be delivered and will not affect the current patient pathway (K4). The new policy specifies delivery of 40Gy in 15 fractions.
	K6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please	K6.2 Not applicable.

	indicate likely outcome for patient at each stopping point.	
K7 Treatment Setting	 K7.1 How is this treatment delivered to the patient? Acute Trust: Inpatient/Daycase/ Outpatient Mental Health Provider: Inpatient /Outpatient Community setting Homecare delivery 	K7.1 This treatment is delivered in an outpatient setting. ^{xx}
	K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? e.g. service capacity	K7.2 No anticipated change in delivery setting or capacity, as this policy is largely already in place.
K8 Coding	K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?	K8.1 All patients undergoing radiotherapy treatment are recorded in the National Radiotherapy Dataset (RTDS) and Secondary Uses Services (SUS) datasets.
	K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	K8.2. Activity could be identified by relevant ICD-10 codes and procedure codes. ^{xxi}
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information	K9.1 No

Schedule? If so, these must be communicated to <u>CTownley@nhs.net</u> , ideally by end of October to inform following year's contract	
K9.2 If this treatment is a drug, what pharmacy monitoring is required?	K9.2 Not applicable.
K9.3 What analytical information /monitoring/ reporting is required?	K9.3 Radiotherapy providers must submit their activity to the national Radiotherapy Dataset (RTDS) on a monthly basis. Reasons for all individual treatments exceeding 15 fractions must be recorded by the trust and may be subject to audit by NHS England.
K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	K9.4 No change required.
K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.5 Not known.
K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	 K9.6 There is a NICE Quality Standard applicable to Breast Cancer (QS12, nice.org.uk/guidance/qs12). Of the 13 quality statements, statements 6 and 8 are applicable to radiotherapy treatment: 6. People with early invasive breast cancer, irrespective of age, are offered surgery, radiotherapy and appropriate systemic therapy,

		unless significant comorbidity precludes it 8. People with early invasive breast cancer are involved in decisions about adjuvant therapy after surgery, which are based on an assessment of the prognostic and predictive factors, and the potential benefits and side effects. The quality standard does not contain reference to the fractionation schedule.
	K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. See also linked question in M1 below	K9.7 No
	Section L - Service	Impact
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	L1.1 Radiotherapy in the NHS in England is delivered by 50 centres; all centres provide radiotherapy for breast cancer.
	L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.2 No change to service organisation.
L2 Geography & Access	L2.1 Where do current referrals come from?	L2.1 Patients referred by MDT following surgery.

	L2.2 Will the new policy change / restrict / expand the sources of referral?	L2.2 No change.
	L2.3 Is the new policy likely to improve equity of access	L2.3 No change from current practice.
	L2.4 Is the new policy likely to improve equality of access / outcomes?	L2.4 No change from current practice.
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?	L3.1 No implementation requirements.
	L3.2 Is there a change in provider physical infrastructure required?	L3.2 No change in provider physical infrastructure.
	L3.3 Is there a change in provider staffing required?	L3.3 No change required.
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	L3.4 No new requirements.

	L3.5 Are there changes in the support services that need to be in place?	L3.5 no change in support services.	
	L3.6 Is there a change in provider / inter- provider governance required? (e.g. ODN arrangements / prime contractor)	L3.6 No change in governance required.	
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	L3.7 No change in the number of providers anticipated.	
	L3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	L3.8 No	
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)?	L4.1 Not known.	
	Section M - Finance Impact		
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)	
M1 Tariff	M1.1 Is this treatment paid under a	M1.1 This treatment is paid under national tariff and falls under the	

	national prices*, and if so which?	HRG codes: SC45Z for planning and SC23Z for the delivery of one fraction of radiotherapy. ^{xxii}
	M1.2 Is this treatment excluded from national prices	M1.2 No
	M1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?	M1.3 No
	M1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes	M1.4 Not applicable.
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 Not applicable.
	M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	M1.6 No
M2 Average Cost per Patient	M2.1 What is the revenue cost per	M2.1 The revenue cost per patient is estimated at c. £2,413 in the first

	patient in year 1?	year. This comprises c. £417 for the planning session of radiotherapy treatment and c. £1,997 for the delivery of 15 fractions of radiotherapy (£133 × 15). ^{xxiii}
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 This is a one off treatment. No further changes to the patient pathway beyond the first year were identified.xxiv
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England	M3.1 Cost neutral.
		As outlined in K1.2, as of 2014/15, 88% of the patients were already receiving the standard 15 fractions of radiotherapy (following the policy statement issued in 2015). As such, the cost impact of this policy is estimated to be nil.
		[Note: Previous to the 2015 policy statement, c.72% of the patients were receiving the standard 15 fractions. Savings of c. £6m have already been observed.]
	M3.2 Where this has not been identified, set out the reasons why this cannot be measured	M3.2 Not applicable.
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs)	M4.1 Cost neutral. No additional costs to other parts of the NHS were identified.
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a	M4.2 Cost neutral as described in M3.1.

	whole	
	M4.3 Where this has not been identified, set out the reasons why this cannot be measured	M4.3 Not applicable.
	M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.4 None identified.
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified <i>e.g.</i> <i>decommissioning less clinically or cost-</i> <i>effective services</i>	M5.1 Not applicable.
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy?	M6.1 The possible savings associated with the policy depend on how many patients adhere to a 15 fraction schedule. If adherence remains as it is currently (88%), there would be no savings. If it increases or decreases, this would generate savings or cost pressure.
	M6.2 Can these be mitigated, if so how?	M6.2 None identified.
	M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and	M6.3 A range is estimated with a current (cost neutral) scenario where adherence to the schedule does not change from 88%. If 5 percentage points more or fewer were to adhere to the 15 fraction schedule, there could be £1.9m cost pressure to £1.9m savings in

	most likely total cost scenarios?	2017/18.
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? <i>e.g. NICE appraisal, clinical trials or peer reviewed literature</i>	M7.1 Three studies reviewed in meta-analysis (Zhou et al., 2015) and Rajagopalan et al, 2015 have compared the total costs of 16 fractions HFRT to those of CFRT. They have all concluded that HFRT to be 10% to 30% lower cost than CFRT, depending on assumptions and specifics of the healthcare.
	M7.2 What issues or risks are associated with this assessment? <i>e.g. quality or availability of evidence</i>	M7.2 None of the studies were based on the UK healthcare system.
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs, periodical costs</i>	M8.1 No
	M8.2 If so, confirm the source of funds to meet these costs	M8.2 Not applicable.

ⁱ This policy formalises the 2015 commissioning policy statement (B01/PS/d: Radiotherapy after primary surgery for breast cancer) which stated that "NHSE would expect 80% or more of the total breast radiotherapy episodes to receive no more than 15 fractions of external beam therapy as the standard core treatment".

ⁱⁱ Based on a 20 year prevalence of 412,506 in 2010 [Source: Macmillan-NCIN Cancer Prevalence Project (2015). 20-year cancer prevalence in the UK]. This number is grown by population growth rates for England since 2010 to obtain a figure for 2014/15 [Source: Office of National Statistics (ONS) (2013), "Population Estimates for UK, England and Wales, Scotland and Northern Ireland, Mid-2001 to Mid-2010 Revised", ONS (2012) "Population Estimates for England and Wales, Mid-2011 (2011 Census-based)" and ONS (2012), Population projections]. The ONS rate has been used in view of uncertainty surrounding future treatment pathways and survival.

ⁱⁱⁱ Crude incidence rates drawn from policy statement (as sourced in footnote i) and ONS population estimates applied (as sourced in footnote ii). This is triangulated against a reported incidence of c. 41,800 in 2011 which is grown by the average incidence growth rate between 2007 and 2012 to arrive at 2014/15 figures. Source: Cancer Research UK. Breast cancer incidence by sex and UK region.[Online] Available from http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer/incidence-invasive#heading-Zero [Accessed: 11/11/2015], National Institute for Health Research (2014). *Neratinib for HER2-positive early breast cancer.* [Online] Available from http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer/ [Accessed: 11/11/2015], National Institute for Health Research (2014). *Neratinib for HER2-positive early breast cancer.* [Online] Available from http://www.hsric.nihr.ac.uk/topics/neratinib-for-her2-positive-early-breast-cancer/ [Accessed: 07/12/2015] and ONS Cancer Registration Statistics (2012)].

^{iv} NICE Guidelines [CG80]. (2009) *Early and locally advanced breast cancer: diagnosis and treatment*. [Online] Available from: <u>https://www.nice.org.uk/guidance/cg80/chapter/1-Guidance</u>. [Accessed 05/11/2015].

^v Based on a reported 31,000 episodes in 2013 [Source: Clinical Priorities Advisory Group (CPAG) (2014)], which is grown by one year to arrive at the 2014/15 figure (growth rate outlined in question K1.7). As discussed with the policy working group, episodes serve as a proxy for the number of patients.

^{vi} The 88% figure represents actual achievement by Q1 2015. Note that this figure is higher than the target initially set out in CPAG (2014), which aimed at a rate of at least 80%. [Source: Discussions with the policy working group based on data from the National Radiotherapy Dataset (RTDS)].

vii Based on diagnoses by age from ONS Cancer Registration Statistics (2012).

viii This is based on a reported number of 'excess fractions' of 14,804, which applies to 1,700 patients [Source: CPAG (2014)]. This results in 7-8 'excess fractions' per patient. Hence those patients on average receive 23-24 fractions.

^{ix} As such, incidence would be more relevant to the costs, rather than prevalence rates.

* Prevalence rates as defined in K1.1 are grown in line with demographic growth projections for the population of England [Source: ONS (2012). Population projections]. Based on discussions with the policy working group, historic incidence growth rates were not used as it is uncertain how future diagnosis rates and survival will evolve.

xⁱ Based on demographic growth projections for the population of England [Source: ONS (2012). Population projections. Based on discussions with the policy working group, historic growth rates in incidence were not used as it is uncertain how future diagnosis rates will evolve.

xii Based on discussions with the policy working group.

xⁱⁱⁱ This assumes that under the 'do nothing' 88% of the eligible patients would receive 15 fractions of radiotherapy and that activity grows in line with projected demographic growth of the population of England as sourced in footnote ii. [Source: CAPG (2014) and discussions with the policy working group].

x^{iv} These prevalence rates have been age standardised for geographical benchmarking and are therefore not the same as the prevalence rates outlined in K1.1 which refers to the actual prevalence. Also, this relates to at most 10 year prevalence, whilst K1.1 considers 20 year prevalence rates. Based on National Cancer Intelligence Network (NCIN) (2006). "One, Five and Ten Year Cancer Prevalence by Cancer Network, UK".

** NHS England Interim Clinical Commissioning Policy Statement: Radiotherapy after primary surgery for breast cancer: (B01/PS/d) (2015).

x^{vi} Sources: Cancer Research UK. *Breast cancer risk factors overview.* [Online] Available from: <u>http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/breast-cancer/risk-factors#heading-Zero</u> [Accessed: 05/11/2015].

^{xvii} As based on discussions with the policy working group.

^{xviii} Based on discussions with the policy working group.

xix This assumes that 88% of the eligible patients would receive 15 fractions of radiotherapy and that activity grows in line with projected demographic growth of the population of England as sourced in footnote ii. [Source: CAPG (2014) and discussions with the policy working group].

^{xx} NHS Choices. *Radiotherapy – How is it performed*. [Online] Available from: <u>http://www.nhs.uk/Conditions/Radiotherapy/Pages/How-it-is-performed.aspx</u> [Accessed: 11/11/2015]

^{xxi} The ICD-10 code for breast cancer is C50 and the OPCS code of the procedure is: X654 - Delivery of a fraction of external beam radiotherapy NEC based on discussions with the policy working group and the CAPG (2014) document.

xxii Based on CPAG (2014).

xxiii Based on 2014/15 tariff for unbundled services (HRG codes SC45Z and SC23Z). Moreover, an uplift factor for the Market Forces Factor (MFF) of 10% is added to the costs (based on discussions with NHS England finance lead).

^{xxiv} Based on discussions with the policy working group.